# IN THE FEDERAL COURT OF AUSTRALIA

# DISTRICT REGISTRY

## NOTICE OF FILING

This document was filed electronically in the Federal Court of Australia on 12 May, 2010

## CASE DETAILS

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| **Case Number:** | NSD 1991 OF 2008 |
| **Case Description:** | PHARM-A-CARE LABORATORIES PTY LTD V COMMONWEALTH OF AUSTRALIA & ANOR |
| **District Registry:** | New South Wales |
| **Document Type:** | Defence |


**Dated:** 12 May, 2010

**Registrar**

**Note**

This Notice forms part of the document and contains information that might otherwise appear elsewhere in the application. The Notice must be included in the document served on each party to the proceeding.

**IN THE FEDERAL COURT OF AUSTRALIA**
**NEW SOUTH WALES DISTRICT REGISTRY**

No. NSD 1991 of 2008

**Pharm-a-Care Laboratories Pty Ltd** ACN 003 468 219

Applicant

**Commonwealth of Australia** & Others

Respondents

FORM 16

**DEFENCE**

(Order 11, rule 20)

## A. Formal Matters

### The Applicant

1 The first respondent (**the Commonwealth**) admits the allegations in paragraph 1 of the FASC (the **FASC**).

2 In answer to paragraph 2 of the FASC, the Commonwealth:

(a) admits that the applicant (**Pharm-a-care**) was, in the period 1 May 2002 to May 2003, engaged in the business of arranging for the manufacture and supply of therapeutic goods;

(b) admits that Pharm-a-care was a "sponsor" for the manufacture of therapeutic goods as defined in the *Therapeutic Goods Act 1989* (**TG Act**);

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(c) admits that Pharm-a-care was, in the conduct of its business, subject to and potentially affected by the provisions of and the exercise of powers under the TG Act;

(d) otherwise does not admit the allegations in paragraph 2 of the FASC.

**The Group Members**

3 In answer to paragraph 3 of the FASC, the Commonwealth:

(a) admits that Pharm-a-care purports to bring this proceeding as a representative proceeding under the provisions of Part IVA of the *Federal Court Act 1976* (Cth);

(b) admits that the group members on whose behalf Pharm-a-care brings these proceedings are said to be those described in paragraph 3 of the FASC;

(c) otherwise does not admit the allegations in paragraph 3 of the FASC.

**The TGA**

4 In answer to paragraph 4 of the FASC, the Commonwealth:

(a) admits that the TG Act is an Act of the Commonwealth Parliament;

(b) says that it is an object of the TG Act to:

(i) provide for the establishment and maintenance of a national system of controls relating to the quality, safety and efficacy, and timely availability of therapeutic goods that are used in Australia, whether produced in Australia or elsewhere, or exported from Australia;

(ii) provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons;

(c) admits the allegations in paragraph 4(b);

(d) otherwise does not admit the allegations in paragraph 4 of the FASC.

5 The Commonwealth admits the allegations in paragraph 5 of the FASC.

6 The Commonwealth admits the allegations in paragraph 6 of the FASC.

7 In answer to paragraph 7 of the FASC, the Commonwealth:

(a) admits that, at all relevant times, the Therapeutic Goods Administration (**TGA**), as a unit of the Commonwealth Department for Health and Ageing, was responsible for administering the TG Act on behalf of the Minister;

(b) admits that certain officers and employees of the Commonwealth assigned to the TGA were delegates of the Secretary, or of the Minister, for the purposes of the exercise of certain powers under the TG Act and that, in exercising those powers, those persons exercised part of the executive power of the Commonwealth;

(c) otherwise does not admit the allegations in paragraph 7 of the FASC.

8 The Commonwealth does not plead to paragraph 8 of the FASC because that paragraph contains no allegations.

9 In answer to paragraph 9 of the FASC, the Commonwealth says that, at all relevant times:

***Regulation of the manufacture of therapeutic goods:***

(a) pursuant to section 35 of the TG Act it was an offence for a person, at premises in Australia, to carry out a step in the manufacture of therapeutic goods (other than exempt goods under section 18A) for supply for use in humans unless:

(i) the goods are exempt goods or the person is an exempt person in relation to the manufacture of the goods;

(ii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises;

(b) pursuant to section 36 of the TG Act the Minister for Health and Ageing (**the Minister**), or her delegate under section 57 of the TG Act (**delegate**), was empowered to determine written principles to be observed in the manufacture of therapeutic goods for use in humans (**manufacturing principles**) which may relate to:

(i) the standards to be maintained, and the equipment to be used at premises used for manufacturing therapeutic goods for use in humans;

(ii) procedures for quality assurance and quality control to be employed in the manufacturing of therapeutic goods for use in humans;

(iii) the qualifications and experience of persons employed in the manufacture of therapeutic goods for use in humans;

(iv) other matters relevant to the quality, safety and efficacy of therapeutic goods for use in humans that are manufactured in Australia;

(v) may include codes of good manufacturing practice (**GMP**);

(c) pursuant to section 38 of the TG Act the Secretary of the Department of Health and Ageing (**the Secretary**) or her delegate was required to grant an applicant for a licence to manufacture therapeutic goods a licence (**licence**) if certain conditions relating to the application are satisfied, unless:

(i) the Secretary is satisfied that the person will be unable to comply with the manufacturing principles or the premises are not satisfactory for the manufacture of therapeutic goods;

(ii) the person has had a licence previously revoked;

(iii) the person, or a body corporate he or she controls or controlled, has been convicted of an offence against the TG Act or a law of a State or Territory relating to therapeutic goods;

(iv) the person is controlled by another person who has been convicted of an offence against the TG Act or a law of a State or Territory relating to therapeutic goods;

(v) the person has failed on more than one occasion to observe the manufacturing principles in connection with the manufacture of therapeutic goods;

(d) pursuant to sections 40(1) and (2) of the TG Act:

(i) a licence may be granted subject to conditions designed to ensure that the holder of the licence manufactures the goods in accordance with the manufacturing principles and any standards applicable to the goods, and such other conditions relating to the manufacture of therapeutic goods as the Secretary or her delegate thinks appropriate;

(ii) the Secretary or her delegate may, by notice in writing given to the holder of the licence, impose new conditions on the licence or vary or remove existing conditions;

(e) pursuant to section 40(4) of the TG Act, in addition to any other condition, a licence, except as otherwise specified in the licence, is subject to a condition that the holder of the licence will *inter alia*:

(i) ensure that the goods conform to any standard applicable to the goods;

(ii) allow an authorised person:

(A) to enter, at any reasonable time, the manufacturing premises to which the licence relates;

(B) while on the premises, to inspect those premises, any therapeutic goods manufactured at those premises and processes relating to the manufacture, and to take samples of goods of that kind and, with the agreement of the holder, to take photographs of those premises, goods or processes;

(iii) upon an authorised person entering premises, require the holder or his or her employees at those premises to answer questions relating to procedures carried out at the premises;

(iv) if requested to do so by an authorised person, produce such documents relating to the manufacture of therapeutic goods manufactured at the premises as the person requires and allow the person to copy the

documents or produce to the person for examination any batch samples kept by the holder;

(f) pursuant to section 41 of the TG Act, the Secretary or her delegate may by notice in writing given to the holder of the licence revoke or suspend the licence for a period specified in the notice if *inter alia*:

(i) the holder of the licence, or a body corporate the holder controls, controlled or is controlled by, has been convicted of an offence against the TG Act or a law of a State or Territory relating to therapeutic goods;

(ii) the holder has breached a condition of the licence;

(iii) the holder has failed to observe the manufacturing principles;

***Regulation of the supply of therapeutic goods:***

(g) pursuant to section 20 of the TG Act, it was an offence for a person, being a sponsor of certain therapeutic goods, to import into Australia, export from Australia, manufacture in Australia, or supply in Australia those therapeutic goods for use in humans if the goods are not registered goods or listed goods in relation to that person, or are not exempt goods or are not the subject of approval or authority under sections 19 or 19A of the TG Act;

(h) pursuant to section 21 of the TG Act, it was an offence for a person, not being a sponsor of therapeutic goods, to supply those therapeutic goods for use in humans in Australia to a person who is not the ultimate consumer of the goods unless the goods are registered goods or listed goods, or are exempt goods or are the subject of approval or authority under sections 19 or 19A of the TG Act;

(i) pursuant to Chapter 3, Part 3-2, Division 2 of the TG Act, where an application is made for the registration or listing of therapeutic goods, the Secretary or her delegate was empowered to register or list on the Australian Register of Therapeutic Goods (**ARTG**) those therapeutic goods if certain conditions relating *inter alia* to the quality, safety and efficacy of the therapeutic goods, the

presentation of the goods and the standard of the manufacture of the goods are satisfied;

(j) pursuant to sections 28(1) and (2) of the TG Act, where the Secretary or her delegate includes therapeutic goods on the ARTG in relation to a person, the Secretary may impose conditions on the listing or registration of the goods, which conditions may relate to *inter alia*:

(i) the manufacture of the goods;

(ii) the custody, use, supply, disposal or destruction of the goods;

(iii) the keeping of records in relation to the goods;

(k) pursuant to section 28(3) of the TG Act the Secretary or her delegate may by notice in writing to the person in relation to whom therapeutic goods are registered or listed on the ARTG impose new conditions on the registration or listing, or vary or remove existing conditions;

(l) pursuant to section 30(1) of the TG Act, the Secretary or her delegate may cancel the registration or listing of therapeutic goods on the ARTG if *inter alia*:

(i) it appears to the Secretary or her delegate that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury;

(ii) it appears to the Secretary that the quality, safety or efficacy of therapeutic goods is unacceptable;

(m) pursuant to section 30(6) of the TG Act, where the Secretary or her delegate cancels the registration or listing of goods in relation to a person, the Secretary or her delegate may impose on the person a requirement to *inter alia* take steps to recover any of the goods that have been distributed;

(n) otherwise does not admit the allegations in paragraph 9 of the FASC.

**The Respondents**

10 In answer to paragraph 10 of the FASC, the Commonwealth:

(a) admits that at all relevant times the second respondent (**Slater**) was the National Manager of the TGA;

(b) says that the third respondent (**Maclachlan**) was:

(i) prior to 17 January 2003, the Director of the Conformity Assessment Branch of the TGA;

(ii) from 17 January 2003, the Director of the Office of Devices, Blood and Tissues (the **ODBT**) of the TGA;

(iii) at all relevant times, a delegate of the Secretary for the purposes of section 41 of the TG Act;

(c) says that the fourth respondent (**Cesarin**) was:

(i) from September 2002, the Director of the Non-Prescription Medicines Branch of the TGA;

(ii) at all relevant times, a delegate of the Secretary for the purposes of sections 28, 30(1) and 30(6) of the TG Act;

(d) says that the fifth respondent (**Tribe**) was:

(i) prior to 17 January 2003, Chief GMP Auditor in the GMP Audit and Licensing Section of the Conformity Assessment Branch of the TGA;

(ii) from 17 January 2003, Chief GMP Auditor in the Manufacturers Assessment Section of the ODBT of the TGA;

(e) says that the sixth respondent (**Fraser**) was:

(i) prior to 17 January 2003, a GMP auditor in the GMP Audit and Licensing Section of the Conformity Assessment Branch of the TGA;

(ii) from 17 January 2003, a GMP auditor in the Manufacturers Assessment Section of the ODBT of the TGA;

(iii) was assigned to lead two GMP audits of Pan Pharmaceuticals Ltd (**Pan**) in 2003, the first of which occurred on 30 and 31 January 2003, and the second of which occurred on 24 and 25 February 2003 and 7 – 11 and 14 April 2003;

(f) otherwise does not admit the allegations in paragraph 10 of the FASC.

11 In answer to paragraph 11 of the FASC, the Commonwealth:

(a) repeats paragraph 10 above;

(b) admits that each of Slater, Maclachlan, Cesarin, Tribe and Fraser were engaged by the Commonwealth pursuant to the *Public Service Act 1999* (Cth);

(c) admits that each of Slater, Maclachlan, Cesarin, Tribe and Fraser received a salary as an employee of the Commonwealth;

(d) admits that each of Slater, Maclachlan, Cesarin, Tribe and Fraser was, in the position pleaded in paragraph 10 above, an officer of the Commonwealth within the meaning of section 75(v) of the Constitution;

(e) otherwise does not admit the allegations in paragraph 11 of the FASC.

## B. BACKGROUND FACTS AND CIRCUMSTANCES

### Pan Pharmaceuticals

12 In answer to paragraph 12 of the FASC, the Commonwealth:

(a) says that from a date no earlier than 23 December 1999, Gemal Sami Selim (**Selim**) was a director and Chief Executive Officer (**CEO**) of Pan;

(b) says that Selim was required by the Board of Pan to resign as CEO on 1 May 2003;

(c) otherwise does not admit the allegations in paragraph 12 of the FASC.

13 In answer to paragraph 13 of the FASC, the Commonwealth says that:

(a) on 8 November 1974 Pan Laboratories Pty Limited (**Pan Labs**) was incorporated;

(b) on 4 May 1989 Pan Laboratories (Australia) Pty Limited (**Pan Labs Australia**) was incorporated;

(c) on 23 December 1999, Pan was incorporated as a proprietary company with the name "Pan Pharmaceuticals Pty Limited";

(d) on 9 June 2000 Pan became a public company and changed its name to "Pan Pharmaceuticals Ltd";

(e) each of the companies referred to in paragraphs (a) to (d) above was engaged in the manufacture of therapeutic goods;

(f) otherwise does not admit the allegations in paragraph 13 of the FASC.

14 In answer to paragraph 14 of the FASC, the Commonwealth:

(a) says that Pan held a licence under the TG Act to manufacture therapeutic goods from its premises at Moorebank, Sydney from 22 March 2000;

(b) otherwise does not admit the allegations in paragraph 14 of the FASC.

15 In answer to paragraph 15 of the FASC, the Commonwealth:

(a) says that, as at 30 June 2002, there were 5,719 products on the ARTG in respect of which Pan was identified as a possible manufacturer of that product;

(b) says that of those 5,719 products:

(i) 314 were registered products;

(ii) 5,405 were listed products, 2018 of which were listed as export only;

(c) says that as at 30 June 2002, Pan was the sponsor of 1,824 products on the ARTG, in relation to which:

(i) 1,695 were products listed as export only products;

(ii) all of which were listed products;

(d) says that, in addition, Pan manufactured goods that were not on the ARTG such as veterinary therapeutic goods, including (for example) veterinary antibiotics such as doxycycline;

(e) otherwise does not admit the allegations in paragraph 15 of the FASC.

16 In answer to paragraph 16 of the FASC, the Commonwealth:

(a) repeats paragraph 15 above;

(b) relies on the matters set out in paragraph 17 below;

(c) otherwise does not admit the allegations in paragraph 16 of the FASC.

17 In answer to paragraph 17 of the FASC, the Commonwealth:

(a) says that therapeutic goods included in the ARTG are divided into two categories, being registered goods and listed goods;

(b) says that therapeutic goods are eligible to be listed goods only when they contain well known, established ingredients which have been pre-assessed by the TGA as safe for inclusion in medicines and do not contain ingredients listed or covered by the Standard for the Uniform Scheduling of Drugs and Poisons;

(c) says that therapeutic goods which are not eligible to be listed goods on the ARTG are required to be registered goods;

(d) says that therapeutic goods which are listed goods, when properly manufactured according to the conditions of their listing on the ARTG and any applicable manufacturing principles and standards, are considered to be lower risk than registered goods;

(e) otherwise does not admit the allegations in paragraph 17 of the FASC.

18 In answer to paragraph 18 of the FASC the Commonwealth:

(a) says that between January 2003 and March 2003 Pan manufactured a large number of tablets and capsules;

(b) otherwise does not admit the allegations in paragraph 18 of the FASC.

19 The Commonwealth does not admit the allegations in paragraph 19 of the FASC.

20 The Commonwealth does not admit the allegations in paragraph 20 of the FASC.

21 In answer to paragraph 21 of the FASC, the Commonwealth:

(a) admits that, at all material times, Pan manufactured tablets and capsules for other companies and businesses for supply in Australia and elsewhere;

(b) says that persons who arranged for Pan to manufacture for supply in Australia or elsewhere therapeutic goods were (unless that person acted on behalf of another person who is a resident of or carries on business in Australia) "sponsors" within the meaning of the TG Act;

(c) otherwise does not admit the allegations in paragraph 21 of the FASC.

22 The Commonwealth does not admit the allegations in paragraph 22 of the FASC.

23 The Commonwealth does not admit the allegations in paragraph 23 of the FASC.

24 In answer to paragraph 24 of the FASC, the Commonwealth:

(a) admits that there were persons who supplied goods and services to Pan in connection with the manufacture and supply of Pan products;

(b) otherwise does not admit the allegations in paragraph 24 of the FASC.

25 In answer to paragraph 25 of the FASC, the Commonwealth:

(a) admits that products manufactured by Pan were distributed by persons to retailers for sale to consumers;

(b) otherwise does not admit the allegations in paragraph 25 of the FASC.

26 The Commonwealth does not plead to paragraph 26 of the FASC because that paragraph contains no allegations.

**TGA Practice and Pan Pharmaceuticals**

27 In answer to paragraph 27 of the FASC, the Commonwealth:

(a) admits that there was in operation at all relevant times from 17 April 1998, version 8 of a TGA Standard Operating Procedure, number 401.8 entitled "GMP Auditing of Medicinal Product Manufacturers" (**SOP 401.8**);

(b) says that SOP 401.8 stated that a final GMP Audit Report should be sent to the subject of a GMP audit as soon as practicable and not later than two weeks from the date of the completion of the audit for domestic audits and six weeks from the date of the audit for overseas audits;

(c) denies that SOP 401.8 contains any provisions to the effect alleged in paragraphs (a) and (c) to (e) of paragraph 27 of the FASC;

(d) otherwise does not admit the allegations in paragraph 27 of the FASC and relies on SOP 401.8 for its full force and effect.

28 In answer to paragraph 28 of the FASC, the Commonwealth:

(a) repeats paragraph 27 above;

(b) says that SOP 401.8 was an operating procedure applicable to audits of all medicinal product manufacturers in Australia and overseas undertaken by the TGA;

(c) otherwise does not admit the allegations in paragraph 28 of the FASC.

29 In answer to paragraph 29 of the FASC, the Commonwealth:

(a) repeats paragraphs 27 and 28 above;

(b) otherwise does not admit the allegations in paragraph 29 of the FASC.

30 In answer to paragraph 30 of the FASC, the Commonwealth:

(a) says that between February 1992 and January 2003 Pan Labs' or Pan's manufacturing facilities at, initially, Villawood and subsequently Moorebank, were subject to GMP audits on 12 occasions;

(b) says that on each occasion, except two, GMP deficiencies were detected as a result of the audit;

(c) says that it was the practice of Pan to make special preparations for announced audits by the TGA including by doing the following:

(i) sanitising batch records of products manufactured by Pan to remove from them things the TGA might object to such as:

(A) instances where decisions of the Quality Control Manager or the Quality Assurance Manager had been overridden by other management;

(B) records of unauthorised deviations in the manufacture of medicines by Pan from the approved formulations for the medicines on the ARTG;

(ii) closing the factory and ceasing production for the whole day prior to the audit to clean up the factory;

(iii) updating standard operating procedure documents and removing superseded versions;

(iv) updating specifications for the testing of raw materials and finished products to comply with the requirements of the TGA;

(d) admits that Tribe issued to Pan certificates of GMP compliance in 1992, 1993, 1994, 1995, 1996, 1997, 2000 and 2001;

(e) otherwise does not admit the allegations in paragraph 30 of the FASC.

31 In answer to paragraph 31 of the FASC, the Commonwealth:

(a) repeats paragraph 13 to 30 above; and;

(b) admits that the matter pleaded in paragraph 19 of the FASC is referred to in an email from Slater to Jane Halton (the Secretary of the Department of Health and

Ageing) which was copied to *inter alia* Maclachlan, Cesarin and Tribe and dated 20 March 2003;

(c) admits that the matter pleaded in paragraph 20 of the FASC was referred to in a document attached to an email from Maclachlan to Anthony Gould, the then Deputy Chief GMP Auditor at the TGA (**Gould**), which was copied to *inter alia* Tribe and is dated 30 March 2003;

(d) otherwise does not admit the allegations in paragraph 31 of the FASC.

## C. CHRONOLOGY OF EVENTS

### TGA Audit of Pan in May 2002

32 In answer to paragraph 32 of the FASC, the Commonwealth:

(a) admits that from 30 April to 1 May 2002 Dr David Buckley and Robert Prestridge (**Prestridge**), being GMP auditors within the TGA, conducted a GMP audit on Pan;

(b) says that on 6 and 7 May 2002 Dr Buckley and Prestridge produced a GMP audit report (**2002 Audit Report**) which stated *inter alia* that *"[t]he auditors considered that the company could have an acceptable level of [GMP] compliance subject to satisfactory responses to non-conformities observed at the present audit"*;

(c) says that the 2002 Audit Report identified 12 significant non-conformities in Pan's compliance with the Australian Code of Good Manufacturing Practice for Therapeutic Goods – Medicinal Products published by the Commonwealth Department of Community Services and Health in August 1990 which was given legal effect by section 36 of the TG Act (the **1990 GMP Code**) and was required to be complied with by manufacturers holding licences under the TG Act, including Pan;

(d) repeats paragraph 30(d) above;

(e) otherwise does not admit the allegations in paragraph 32 of the FASC and relies on the 2002 Audit Report for its full force and effect.

**Travacalm**

33 In answer to paragraph 33 of the FASC, the Commonwealth says that:

***Travacalm, hyoscine hydrobromide and uniformity of content testing:***

(a) in May and June 2002 Pan commenced to manufacture medicines called Travacalm and Travacalm HO (collectively, **Travacalm**) for Key Pharmaceuticals Pty Limited (**Key**);

(b) Pan manufactured batches of Travacalm with batch numbers 77163, 77164, 78586, 79376 and 79954;

(c) Travacalm was and is a registered medicine on the ARTG, the active ingredient of which is hyoscine hydrobromide and is and was known as a "microdose" product;

(d) under Therapeutic Goods Order No 56 (**TGO 56**), made pursuant to section 10 of the TG Act, and the British Pharmacopeia (**BP**), Travacalm was required to comply with uniformity of content testing;

(e) TGO 56 and the BP required 10 doses of Travacalm randomly selected to be tested after manufacture and for those tests to establish that in all 10 sample doses the content of the active ingredient (hyoscine hydrobromide) was between 85% and 115% of the specified amount;

(f) says that by at least May 2002 and continuing to on or about 28 April 2003:

(i) uniformity of content testing at Pan was carried out by high performance liquid chromatography (**HPLC**) testing which was processed on a computer installed in the laboratory at Pan (the **HPLC Computer**);

(ii) it was the practice of Pan to manipulate the results of HPLC testing when that testing produced results which were out of specification;

(iii) at least two analysts employed by Pan, Shyama Jain (**Jain**) and Simon Fernandez (**Fernandez**), had been shown how to manipulate data produced by HPLC testing by Joseph Iaquinto (**Iaquinto**), a senior analyst

employed by Pan and second in charge to Pan's Quality Control Manager, Shrikant Dhumal (**Dhumal**);

(iv) Jain and Fernandez routinely manipulated test results to bring them into specification by moving the "peak markers" on the chromatogram and did so to the knowledge of and in consultation with Iaquinto and Dhumal;

(v) where the test results of a chromatogram could not be brought into specification by moving the "peak markers" on the chromatogram, Iaquinto would produce a substitute chromatogram by using the results of a different test and misrepresenting that test as the results of the test which had failed testing;

(vi) Dr John Brennan (**Brennan**), the General Manager of Pan, frequently instructed employees of Pan, including but not limited to Jain, to manipulate test results for products to change out of specifications results to within specification and to substitute out of specification results of testing conducted by external testers (such as Amdel) with test results which were within specification;

(vii) raw materials were frequently not tested or the results of testing were fabricated and this was approved by Brennan and Selim;

(viii) finished products were being released for supply to customers prior to testing being completed at the direction of Brennan or Selim;

(ix) where Pan was making a product and had insufficient quantity of active materials, it would simply make up the difference using inactive material or bulking agent;

(x) machinery was not cleaned between batches because it would mean the time available for production would be restricted;

(g) says that Jain had personally manipulated the results of HPLC testing on hundreds of products while employed at Pan by moving the "peak markers" on the chromatogram pursuant to the practice referred to in subparagraph (f) above;

(h) says that the batches of Travacalm with batch numbers 77163, 77164, 78586, 79376 and 79954 were tested by Pan after manufacture using HPLC testing and failed uniformity of content testing;

(i) says that, pursuant to the practice referred to in subparagraph (f) above, Pan (through Jain, Dhumal and Iaquinto) deliberatively manipulated the results of the HPLC testing for the Travacalm batches numbered 77163, 77164, 79376 and 79954 and that Pan (through Fernandez, Dhumal and Iaquinto) deliberately manipulated the results of the HPLC testing for the Travacalm batch numbered 78586;

(j) says that Pan issued analytical reports for the batches of Travacalm numbered 77163, 77164, 78586, 79376 and 79954 which it knew falsely asserted that the batches had the required uniformity of content and supplied the batches of Travacalm numbered 77163, 77164, 78586, 79376 and 79954 to Key knowing that that they failed uniformity of content testing and did not have uniformity of content;

(k) an overdose of hyoscine hydrobromide can cause serious psychotic reactions, including unconsciousness, hallucination and delirium;

***Adverse reactions to Travacalm in December 2002 – January 2003:***

(l) in December 2002 and January 2003 Key and the TGA received a number of adverse reaction reports from persons who had experienced adverse reactions after taking Travacalm;

(m) the adverse reactions suffered by persons who had taken Travacalm manufactured by Pan in late 2002 / early 2003 included unconsciousness, hallucination and delirium, and involved 18 cases where hospitalisation of the person was required, some in intensive care;

(n) by 16 January 2003 the adverse reaction reports received by Key and the TGA had been connected to three batches of Travacalm manufactured by Pan, being batches 77164, 78586 and 79954;

(o) on 16 January 2003 Tom Gregory, the Chief Executive Officer of Key (**Gregory**), and Sonya Sparre (**Sparre**), also of Key, discussed with officers of the TGA, including Dr John McEwen (**McEwen**), whether to undertake a recall of Travacalm;

(p) by at least 16 January 2003, and likely by 13 January 2003, Selim and Pan were aware of the occurrence of adverse reactions by persons who had taken Travacalm manufactured by Pan and that there was likely to be a recall of Travacalm on 20 January 2003;

**Particulars**

(a) Conversation between Selim and Gregory which occurred on 16 January 2003.

(b) Letter from Pan's Quality Assurance Manager, Sam Elia (**Elia**), to Sparre of Key dated 16 January 2003.

***Recall of Travacalm:***

(q) on 20 January 2003 Key agreed with the TGA to undertake a consumer level recall of three batches of Travacalm manufactured by Pan, batches 77164, 78586 and 79954;

(r) on 20 January 2003 Gregory informed Selim of the decision of Key and the TGA to undertake a consumer level recall of Travacalm;

(s) the Travacalm recall was announced on 21 January 2003, was the subject of press releases of Key and the TGA issued on 21 January 2003 and 22 January 2003 (respectively), and was reported in the media on those days or shortly thereafter;

(t) the recall of Travacalm was designated a Class 1 Recall, meaning that the defects were potentially life threatening or could cause serious risk to health;

(u) on 22 January 2003 testing conducted by the TGA on samples of Travacalm manufactured by Pan disclosed that the content of hyoscine hydrobromide in those batches ranged between 0% and 700% of the specified amount and that none of the batches tested were within specification;

(v) says that on 24 January 2003 Elia retrieved and printed from the HPLC Computer the uniformity of content test results for hyoscine hydrobromide carried out on the Travacalm batches numbered 77164, 78586 and 79954 which showed the true results of each of the batches before they were manipulated (**Raw Travacalm Chromatograms**);

(w) the Raw Travacalm Chromatograms established that the batches of Travacalm manufactured by Pan had failed uniformity of content testing and should have been rejected, but that the results of the uniformity of content testing had been manipulated to produce results within specification;

(x) that likely by 24 January 2003 and in any event by no later than 29 January 2003, Selim and Brennan had obtained the Raw Travacalm Chromatograms and knew (and therefore Pan knew):

(i) that the Raw Travacalm Chromatograms established that the batches of Travacalm manufactured by Pan had failed uniformity of content testing and should have been rejected, but that the results of the uniformity of content testing had been manipulated to produce results within specification;

(ii) that an incorrect method of manufacture of Travacalm had been employed – namely, the "dry-mix granulation" method - which could not possibly have produced a proper uniformity of content of hyoscine hydrobromide;

(y) on 28 January 2003 further testing conducted by the TGA on samples from two other batches of Travacalm manufactured by Pan – batches 77163 and 79376 -

indicated that those batches did not have a uniform distribution of content of hyoscine hydrobromide;

(z) on 28 January 2003 Key undertook a consumer level recall of batches 77163 and 79376 of Travacalm;

(aa) says that at a meeting in the afternoon of 29 January 2003, Selim and Brennan conceived a plan to destroy the Raw Travacalm Chromatograms and to delete the data on the HPLC Computer;

(bb) on about 29 January 2003 Brennan instructed Iaquinto to delete the data on the HPLC Computer;

(cc) on about 29 January 2003 Brennan instructed Elia to destroy the Raw Travacalm Chromatograms, but contrary to the instruction, and without Brennan's knowledge, Elia hid the Raw Travacalm Chromatograms in the bottom drawer in his desk;

***TGA's investigation of Travacalm:***

(dd) on 30 January 2003 and 31 January 2003 Tribe, Fraser and Prestridge conducted an unannounced audit of Pan's premises in order to investigate the circumstances surrounding the manufacture of Travacalm resulting in its recall (**Travacalm audit**);

(ee) at the commencement of the Travacalm audit Tribe, Fraser and Prestridge were advised by Brennan that Pan understood there was a problem with Travacalm and that Pan had started a preliminary investigation but was unable to give any information to explain how the situation could possibly have occurred;

(ff) on the morning of 30 January 2003 Selim instructed Elia not to inform the TGA officers conducting the Travacalm Audit of Pan's conduct in relation to Travacalm because he was "*going to fight them*";

(gg) during the course of the Travacalm audit:

(i) on 30 January 2003, Prestridge asked for and was given the batch records in relation to the five batches of Travacalm manufactured by Pan;

(ii) the Travalcam batch records given to Prestridge included documents called chromatograms which purported to be the results of uniformity of content tests performed by Pan on Travacalm and which showed that the batches of Travacalm had complied with the requirements for uniformity of content of hyoscine hydrobromide in TGO 56 and the BP (**Travacalm Chromatograms**);

(iii) at the time Prestridge was given the batch records, no-one from Pan said to him that the Travacalm Chromatograms in the batch records had been manipulated;

(iv) upon inspection of the Travacalm Chromatograms Prestridge formed the view that the Travacalm Chromatograms contained indications of data manipulation in relation to testing for the uniformity of content of hyoscine hydrobromide;

(v) Prestridge said to Dhumal that it appeared to him that the data contained in the Travacalm Chromatograms had been manipulated so that it would appear that the batches had passed uniformity of content testing;

(vi) Prestridge repeated his concerns about the discrepancies in the test results to Dhumal in the presence of Brennan and Tribe;

(vii) Prestridge asked to inspect the computer which had performed the testing for the uniformity of content of hyoscine hydrobromide in Travacalm to further investigate whether there had been manipulation of data, but was denied access to the HPLC Computer and told that the HPLC Computer had been re-formatted and the data on it had been lost;

(viii) on 30 January 2003, Tribe said to Selim and Brennan that Prestridge had told him that the HPLC Computer had been reformatted and data has been lost that the TGA required for its audit, and that the TGA were extremely concerned about this;

(ix) in about the evening of 30 January 2003 Selim directed Karl Brooks (Pan's IT Manager) (**Brooks**), to perform a "low-level format" to the Computer in order to ensure the data on the HPLC Computer was not retrievable by anyone, including a computer forensics expert;

(x) during the evening of 30 January 2003 Brooks downloaded from the internet a low-level format software tool called "Seagate" and, in the evening of 30 January 2003 and morning of 31 January 2003, used that software to conduct a low-level format on the HPLC Computer;

(xi) the purpose of the destruction of the Raw Travacalm Chromatograms and the purpose and effect of the deletion of the data on the HPLC Computer was to:

(A) to hinder any attempt by any person (including officers of the TGA) to investigate the circumstances leading to the recall of Travacalm;

(B) to hinder any attempt by any person (including officers of the TGA) to investigate the extent of data manipulation occurring within Pan;

(xii) on 31 January 2003 Fraser and Prestridge informed Brennan of their belief that they had found evidence of what they considered to be data manipulation in relation to testing for the uniformity of content of hyoscine hydrobromide in Travacalm;

(xiii) shortly thereafter, Brennan returned to Fraser and Prestridge together with Selim and Shayama Jain (**Jain**) and stated that Jain had performed the data manipulation, had been working alone and did not know why he had done it, and told Jain to confess to Fraser and Prestridge, however, Jain did not do so, remained mute and cried;

***Conversation between Selim and Elia in February 2003:***

(hh) says that, in early February 2003 Elia stated to Selim that Jain should be fired and Selim informed Elia to the effect that Jain would only be given a warning letter because *inter alia* "*no one else will do my dirty work*";

(ii) says that Selim said this to Elia because Jain did in fact do Selim's and Pan's *"dirty work"* in that he manipulated data and test results in order to convey falsely to Pan's customers that therapeutic goods manufactured by Pan were manufactured in accordance with GMP and were within the specifications for the goods;

(jj) otherwise does not admit the allegations in paragraph 33 of the FASC.

**Travacalm Audit Report and variation of Pan's licence to manufacture therapeutic goods**

34 In answer to paragraph 34 of the FASC, the Commonwealth:

(a) repeats paragraphs 33(q) and (z) above;

(b) says that on 5 February 2003 the TGA sent a facsimile to Pan enclosing:

(i) a letter from Maclachlan to Pan dated 5 February 2003 (**5 February 2003 Letter**);

(ii) an audit report dated 5 February 2003 following the Travacalm audit signed by Fraser, Tribe and Prestridge (**Travacalm Audit Report**);

(c) says that the Travacalm Audit ReportTravacalm Audit Report found to the effect that:

(i) Pan had adopted an incorrect method of manufacture of Travacalm involving a "dry-mix granulation" method of manufacture as opposed to the correct "wet-mix granulation" method of manufacture;

(ii) the incorrect method of manufacture of Travacalm was responsible for the uneven distribution of hyoscine hydrobromide throughout the batches of Travacalm manufactured by Pan;

(iii) uniformity of content testing conducted by Pan on initial batches of Travacalm had disclosed the uneven distribution of hyoscine hydrobromide throughout the batches of Travacalm manufactured by Pan;

(iv) notwithstanding (iii) above, Pan did not change the method of manufacture of Travacalm for subsequent batches of Travacalm from the "dry-mix granulation" method to the correct "wet-mix granulation" method;

(v) the uniformity of content testing results of hyoscine hydrobromide in relation to all batches of Travacalm manufactured by Pan had been deliberately and systematically manipulated to produce results for uniformity of content of hyoscine hydrobromide which were within specification when they were not;

(vi) despite (i) to (v) above, Pan released Travacalm for sale to Key;

(vii) there were three "critical deficiencies" in Pan's manufacture of Travacalm, being deficiencies which may produce, or may result in a significant risk of producing, a product that is harmful to the user;

(d) otherwise relies on the Travacalm Audit ReportTravacalm Audit Report for its full force and effect;

(e) says that Pan knew by 16 May 2002 that the "dry-mix granulation" method of manufacture of Travacalm was not the method of manufacture of Travacalm which the TGA had approved when Travacalm was registered on the ARTG and that the "dry-mix granulation" method could not be used for the manufacture of Travacalm without notification of and approval by the TGA;

**Particulars**

Facsimile from Sparre to Brennan dated 16 May 2002.

(f) says that the 5 February 2003 Letter:

(i) noted that the Travacalm Audit Report revealed critical non-compliance with the Therapeutic Goods (Manufacturing Principles) Determination No 2 of 2002 made pursuant to section 36(1) of the TG Act for the manufacture of Travacalm products and other tablet products containing low doses of active ingredients;

(ii) advised that Maclachlan, as a delegate of the Secretary, had decided under section 40(2) of the TG Act to impose a new condition on Pan's licence to manufacture therapeutic goods which condition read "This licence does not authorise the manufacture of any products that would be required by Therapeutic Goods Order No 56 to have a uniformity of content test";

(iii) advised that the variation to Pan's licence would take effect immediately because of an imminent risk of death or serious injury to persons taking tablets requiring uniformity of content testing under TGO 56 that have been manufactured by Pan;

(iv) otherwise relies on the 5 February 2003 Letter for its full force and effect;

(g) otherwise does not admit the allegations in paragraph 34 of the FASC.

35 In answer to paragraph 35 of the FASC, the Commonwealth:

(a) repeats paragraph 34 above;

(b) otherwise does not admit the allegations in paragraph 35 of the FASC.

**Correspondence between the TGA and Pan after the Travacalm Audit Report**

36 In answer to paragraph 36 of the FASC, the Commonwealth:

***Pan's 14 February 2003 letter:***

(a) says that on 14 February 2003 Pan wrote to the TGA responding to the Travacalm Audit Report (**14 February 2003 letter**) in which letter Pan *inter alia*:

(i) stated to the effect that the most critical system failure in relation to Travacalm was the misrepresentation of the analytical result of uniformity of content of hyoscine hydrobromide on all batches of Travacalm;

(ii) stated that the analyst involved had deliberatively manipulated the HPLC analysis chromatograms to obtain a favourable result, and had falsified information and sabotaged an existing and reliable system of quality control testing;

(iii) stated that it felt confident, based on interviews with the analyst and QC Manager, that this was an isolated incident;

(iv) enclosed a document entitled "Report on Travacalm" created by Elia, some time prior to 3 February 2003 (**Report on Travacalm**) which indicated that:

(A) by no later than 29 January 2003 and likely by 24 January 2003 Selim, Brennan and Elia had obtained the Raw Travacalm Chromatograms;

(B) the Raw Travacalm chromatograms established that the batches of Travacalm manufactured by Pan had failed uniformity of content testing and should have been rejected, but that the results of the uniformity of content testing had been manipulated to produce results within specification;

(C) Selim, Brennan and Elia were aware of the matters in (B) above by no later than 29 January 2003 and likely by 24 January 2003;

(D) by no later than 29 January 2003 and likely by 24 January 2003 Selim, Brennan and Elia knew that an incorrect method of manufacture of Travacalm had been employed – namely, the "dry-mix granulation" method - which could not possibly have

produced a proper uniformity of content of hyoscine hydrobromide;

(b) otherwise relies on the 14 February 2003 letter for its full force and effect;

(c) says that the statement in the 14 February 2003 letter in (a)(iii) above was false because by no later than 3 February 2003 and likely by 29 January 2003 Pan knew (because Selim and Brennan knew) that an inspection of the batch records of 30 batches of product other than Travacalm had disclosed evidence of data manipulation in 16 of those batches;

**Particulars**

Document entitled "Chromatograms Investigation".

(d) says that the statements in the "Report on Travacalm" enclosed with the 14 February 2003 letter and referred to in (a)(iv) above were inconsistent with what Brennan had advised Tribe, Fraser and Prestridge at the commencement of the Travacalm audit referred to in paragraph 33(ee) above;

***TGA letter to Pan of 17 February 2003:***

(e) says that on 17 February 2003 the TGA wrote to Pan in response to Pan's letter of 14 February 2003 in which letter the TGA:

(i) noted that it had been observed on 13 February 2003 during the course of an execution of a search warrant on Pan (referred to in paragraph 38 below) that Jain continued to work in Pan's laboratory despite being the person identified by Pan as responsible for sabotage in relation to Travacalm;

(ii) expressed the view that the matter in (i) above was disturbing, constituted an unacceptable risk to the consumer and was arguably contrary to Pan's conclusions presented to date;

(iii) noted that the Report on Travacalm contradicted the position presented by Brennan and other Pan representatives during the Travacalm audit in

which Pan's representatives claimed unawareness of any explanation for the adverse reactions suffered by persons who had taken Travacalm and appeared shocked and surprised when Fraser and Prestridge presented the results of the Travacalm audit;

(iv) stated to the effect that the above matters gave rise to concerns about the general level of credibility of the information provided by Pan;

(v) stated that Pan's response to the Travacalm Audit in its letter of 14 February 2003 was being reviewed in detail, but a number of areas regarded as unsatisfactory had already been identified;

(f) otherwise relies on the letter of 17 February 2003 for its full force and effect;

(g) says that following the TGA's letter of 17 February 2003, Elia caused Jain's work tasks to be changed so that he could only test simple raw materials and could not be involved with testing of finished product, including HPLC testing;

***Pan letter to TGA of 18 February 2003:***

(h) says that on 18 February 2003 Pan sent a facsimile to the TGA in which Pan responded to the letter of 17 February 2003 by stating to the effect that *inter alia*:

(i) Pan did not agree with the suggestion that Jain's continued presence in the laboratory was an unacceptable risk to consumers because he was assigned simple tasks which were double checked by two analysts;

(ii) Pan was in the last stages of investigation to try and determine whether or not Jain's manipulation of data in relation to Travacalm was part of a conspiracy or was an isolated act which did not involve another party;

(iii) Pan only arrived at its conclusions regarding Jain's deliberate falsification of test results for Travacalm on 31 January 2003;

(iv) Jain had admitted his falsification of test results for Travacalm in an interview with Fraser and Prestridge;

(v) it was Selim's advice which had led Fraser, Prestridge and Tribe on a train of enquiry resulting in the discovery of the manipulation of data in relation to Travacalm;

(i) otherwise relies on the facsimile of 18 February 2003 for its full force and effect;

(j) Pan's facsimile of 18 February 2003 was false and misleading in that:

(i) the assertion in subparagraph (h)(i) above falsely suggested that Jain's tasks had been limited in the manner suggested at the time the search warrant was executed on Pan on 13 February 2003 when, in fact, that had only occurred after the TGA's letter of 17 February 2003 as set out in subparagraph (g) above;

(ii) the assertion in subparagraph (h)(ii) above was false because, for the reasons set out in subparagraph (c) above, Pan knew as at 18 February 2003 that the manipulation of test data was not an isolated act in relation to Travacalm;

(iii) the assertion in subparagraph (h)(iii) above was false because, for the reasons set out in subparagraph (a)(iv) above, Pan knew probably by 24 January 2003 and certainly by 29 January 2003 that there had been falsification of test data in relation to Travacalm;

(iv) the assertion in subparagraph (h)(iv) above was false by reason of the matters set out in paragraph 33(gg)(xv) above;

(v) the assertion in subparagraph (h)(v) above was false by reason of the matters set out in paragraph 33(gg) above;

***Pan letter of 3 March 2003:***

(k) says that on 3 March 2003 Pan wrote to the TGA enclosing an amended response to the Travacalm Audit Report;

(l) otherwise relies on the letter of 3 March 2003 for its full force and effect;

***TGA's letter of 7 March 2003:***

(m) says that on 7 March 2003 the TGA wrote to Pan in which letter the TGA:

(i) stated that Pan's responses to the Travacalm Audit Report in its letters of 14 February 2003 and 18 February 2003 had been reviewed and concluded as unsatisfactory in addressing all but one of the items detailed in the Travacalm Audit Report;

(ii) stated in broad terms the basis of that conclusion and enclosed a detailed report giving the reasons for that conclusion;

(iii) stated that the audit of Pan which had occurred on 24 – 25 February 2003 (referred to in paragraph 40 below) had indicated that the deficiencies reported in the Travacalm Audit Report were of a wider nature, that of particular concern was that manipulation of data by Pan was not limited to Travacalm, which undermines Pan's position that the data manipulation was an isolated incident, and that the TGA expected Pan's investigations will be amended to reflect adequately the concern of the TGA that data manipulation was not limited to Travacalm;

(iv) stated that Pan's amended response of 3 March 2003 had not been reviewed at the time of writing the letter of 7 March 2003;

(v) stated that Pan was invited to provide a further response addressing the matters raised in the letter of 7 March 2003 and in the enclosed detailed report, or may choose to wait until the TGA had considered Pan's response of 3 March 2003;

(n) otherwise relies on the 7 March 2003 letter for its full force and effect;

***Meeting of Pan and the TGA on 11 March 2003:***

(o) says that on 11 March 2003 Selim and Brennan together with Val Johanson of the Complementary Health Care Council (**Johanson**) met with Tribe, Fraser and Andrew Muir of the TGA (**Muir**) in which meeting:

(i) Selim produced a further (third) response by Pan to the Travacalm Audit Report which responded to the matters raised in the letter of the TGA of 7 March 2003;

(ii) Johanson suggested, and Tribe and Fraser agreed, that it would be of assistance to the TGA if Pan produced a further, consolidated response to the Travacalm Audit Report;

(iii) Selim and Brennan agreed to produce such a further, consolidated response to the Travacalm Audit Report;

(iv) Fraser and Tribe stated to the effect that the audit of Pan which had occurred on 24 and 25 February 2003 (referred to in paragraph 40 below) had been prevented by Selim from being completed, would need to be completed, but had indicated that the manufacturing deficiencies at Pan were not restricted to Travacalm;

(v) Selim stated to the effect that Pan believed that the manipulation of data was restricted to Travacalm because Pan had gone back a few months and checked the batch records;

(p) the statement of Selim pleaded in paragraph (o)(v) above was false to Selim's knowledge for the reasons pleaded in paragraph 36(c) above;

***TGA's letter of 14 March 2003:***

(q) says that on 14 March 2003 the TGA wrote to Pan requesting Pan to provide its revised response to the Travacalm Audit discussed at the meeting of 11 March 2003 by 21 March 2003;

(r) otherwise relies on the 14 March 2003 letter for its full force and effect;

***Pan's letter of 19 March 2003:***

(s) says that on 19 March 2003 Pan wrote to the TGA in which letter Pan enclosed Pan's consolidated response to the Travacalm Audit, consisting of the original response with additional information;

(t) otherwise relies on the 19 March 2003 letter for its full force and effect;

***Pan's letter of 23 April 2003:***

(u) says that on 23 April 2003 Pan wrote to the TGA:

(i) stating to the effect that the Travacalm recall had shown some weaknesses in Pan's quality systems which were the major contributors to the drug recall;

(ii) enclosing a further response to the Travacalm Audit Report following discussions with Fraser and Dragana Milic (**Milic**) during the course of the audit of Pan from 7 to 14 April 2003 (referred to in paragraph 49 below);

(v) otherwise relies on the 23 April 2003 letter for its full force and effect;

(w) otherwise does not admit the allegations in paragraph 36 of the FASC.

37 In answer to paragraph 37 of the FASC, the Commonwealth:

(a) repeats paragraph 36 above;

(b) otherwise does not admit the allegations in paragraph 37 of the FASC.

**Execution of search warrant on Pan by the Australian Federal Police**

38 In answer to paragraph 38 of the FASC, the Commonwealth:

(a) says that on 13 February 2003 the officers of the Australian Federal Police, with officers from the TGA Surveillance Unit, Fraser and Prestridge in attendance, executed a search warrant on the premises of Pan in relation to suspected offences under section 42E of the TG Act ("dealing with counterfeit therapeutic goods");

(b) during the course of the execution of the search warrant:

(i) Selim initially refused to permit the search warrant to be executed on the basis of an assertion that there was no such offence under the TG Act as dealing with counterfeit therapeutic goods;

(ii) Selim relented when a copy of section 42E of the TG Act was shown to him and explained to him;

(iii) Elia produced from his bottom desk drawer the Raw Travacalm Chromatograms for Travacalm batches 77164, 78586 and 79954 which had been retrieved and printed on 24 January 2003 and which showed the true uniformity of content test results for hyoscine hydrobromide;

(iv) Brennan became visibly angry and upset when Elia produced the Raw Travacalm Chromatograms;

(v) Fraser and Prestridge observed Jain continuing to work in Pan's laboratory conducting analysis of finished products, including analysis using high performance liquid chromatography;

(c) says that the Raw Travacalm Chromatograms had not been produced to Fraser, Tribe or Prestridge by Pan during the Travacalm Audit;

(d) says that the Raw Travacalm Chromatograms confirmed that Travacalm batches 77164, 78586 and 79954 had failed the uniformity of content testing for hyoscine hydrobromide required by TGO 56 and the BP;

(e) says that the Raw Travacalm Chromatograms, when compared to the Travacalm Chromatograms provided to Prestridge on 30 January 2003, confirmed that there had been manipulation of the uniformity of content testing for Travacalm batches 77164, 78586 and 79954;

(f) otherwise does not admit the allegations in paragraph 38 of the FASC.

**Briefs by Slater, Maclachlan and Tribe to the Departmental Secretary, Minister and Prime Minister's Office**

39 In answer to paragraph 39 of the FASC, the Commonwealth:

(a) says that on 26 February 2003 Tribe prepared a document known as a "Current Issues Brief" (**CIB**) entitled "Serious Manufacturing Deficiencies – Pan Pharmaceuticals Sydney" for provision to the Minister for Health and Ageing,

Senator Kay Patterson (the **Minister**), and Parliamentary Secretary, Ms Trish Worth (**Parliamentary Secretary**), and sent it to Maclachlan and Slater for review;

(b) says that in or about late February 2003 Maclachlan prepared a document entitled "Minute to the Minister / Parliamentary Secretary Information Only, Serious Manufacturing Deficiencies – Pan Pharmaceuticals Limited Sydney" for provision to the Parliamentary Secretary and the Minister;

(c) says that on or about 13 March 2003 Tribe, Maclachlan and Slater prepared a CIB entitled "Serious Manufacturing Deficiencies – Pan Pharmaceuticals Sydney (update to CIB of 26 Feb)" for provision to the Minister and the Parliamentary Secretary;

(d) says that on or about 18 March 2003 Tribe and Maclachlan prepared a CIB entitled "Serious Manufacturing Deficiencies – Pan Pharmaceuticals Sydney (update to CIB of 13 March)" for provision to the Minister and the Parliamentary Secretary;

(e) says that on or about 18 March 2003 Maclachlan and Tribe prepared a document known as a "Question Time Brief" (**QTB**) entitled "Serious Manufacturing Deficiencies – Pan Pharmaceuticals Sydney" for provision to the Minister and the Parliamentary Secretary;

(f) says that on 20 March 2003 Slater sent to the Secretary (Ms Jane Halton) an email entitled "Heads up on Pan" and which enclosed a document entitled "Surveillance Report" which discussed Pan;

(g) says that on or about 8 April 2003 Maclachlan and Slater prepared a CIB entitled "Serious Manufacturing Deficiencies – Pan Pharmaceuticals Sydney" for provision to the Minister and the Parliamentary Secretary;

(h) says that on 11 April 2003 Slater signed a document entitled "Minute – Manufacturing Licence Pan Pharmaceuticals Limited" for provision to the Secretary;

(i) says that on or about 11 April 2003 Slater signed a document entitled "Minute – Manufacturing Licence Pan Pharmaceuticals Limited" for provision to the Parliamentary Secretary;

(j) says that on 15 April 2003 Maclachlan and Slater met with the Secretary during which meeting:

(i) the Secretary expressed the view that any possible decision regarding the suspension or revocation of Pan's licence should be based on sound medical advice;

(ii) Slater expressed the view that an external expert committee should be established to advise in relation to any possible decision regarding the suspension or revocation of Pan's licence;

(k) says that on 21 April 2003 Maclachlan prepared a document entitled "Minute to the Minister / Parliamentary Secretary – Investigations into Pan Pharmaceuticals Manufacturing Practices";

(l) says that on 24 April 2003:

(i) Slater sent a facsimile to the Parliamentary Secretary enclosing a copy of the report of the Expert Advisory Group convened by the TGA;

(ii) Slater attended a meeting with the Parliamentary Secretary and Arthur Sinodinos, the Prime Minister's Chief of Staff (**Sinodinos**), in which Pan was discussed;

(iii) Slater sent Sinodinos a facsimile enclosing proposed media releases to be issued in the event of a suspension of Pan's manufacturing licence;

(m) says that on 27 April 2003 Slater sent to the Secretary an email entitled "Final documents", enclosing media releases for the Parliamentary Secretary and the TGA relating to the proposed suspension of Pan's manufacturing licence and a CIB entitled "Suspension of Pan Pharmaceuticals Limited Licence to Manufacture Medicines";

(n) relies on each of the documents referred to above for their full force and effect;

(o) otherwise does not admit the allegations in paragraph 39 of the FASC.

**24 – 25 February 2003 audit of Pan**

40 In answer to paragraph 40 of the FASC, the Commonwealth:

(a) says that on 24 February 2003 Fraser, together with Prestridge, Muir, Robert Spence (**Spence**), Guan Khoo (**Khoo**) and Kevin Grant (**Grant**) (all employees within the TGA) arrived at Pan's premises with the intention of conducting a GMP audit of Pan's premises;

(b) says that the purpose of the audit was to assess Pan's compliance with:

(i) the 1990 GMP Code;

(ii) the Australian Code of Good Manufacturing Practice for Medicinal Products dated 16 August 2002 (the **2002 GMP Code**);

(iii) the conditions specified in Pan's licence;

(iv) the regulatory requirements specified on the ARTG and any other requirements imposed by a delegate of the Secretary upon the listing or registration of a product manufactured by Pan (**marketing authorisation**);

(c) says that the audit had been caused to occur on the basis of the critical deficiencies in the Travacalm Audit Report and an insufficient level of confidence regarding Pan's quality management system;

(d) says that the audit was not limited to the manufacture of a particular product range, but was to be a general audit of Pan's entire manufacturing operations;

(e) says that the audit was intended to occur over 5 days, commencing on 24 February 2003 and concluding on 28 February 2003;

(f) says that Pan was informed that the results of the audit would be referred to Maclachlan, Tribe and an internal review panel for consideration, including the possibility of a further restriction, or suspension or cancellation of Pan's licence;

**Particulars**

Letter of Tribe to Brennan dated 24 February 2003.

(g) says that Selim initially refused to permit any GMP audit of Pan to occur;

(h) says that, after approximately two hours of negotiation, Selim agreed to permit an audit of Pan to occur which audit was restricted to an audit of batch documents to be conducted over two days (24 February 2003 and 25 February 2003), but no audit of Pan's factory was permitted to occur;

(i) says that by reason of the matters in subparagraphs (g) and (h) above, Pan was in breach of the condition of its licence incorporated by section 40(4) of the TG Act and set out in paragraph 9(e) above;

(j) says that TGA write to Pan on 25 February 2003 informing Pan to the effect that the TGA would need to continue its audit of Pan, including auditing Pan's factory, in the next few weeks;

**Particulars**

Letter of Tribe to Selim dated 25 February 2003.

(k) says that at a meeting in the late afternoon or evening of 25 February 2003 between Brennan and Fraser, Fraser informed Brennan to the effect that although the audit of Pan had been abbreviated, it had identified serious GMP deficiencies, including further instances of data manipulation and results fabrication which were not restricted to Travacalm and which undermined the credibility of Pan's claim that Travacalm was an isolated incident;

(l) says that following the incomplete audit of Pan on 24 and 25 February 2003:

(i) Selim asked Elia to inspect the batch records which the officers of the TGA had inspected when conducting the audit and form a view as to what deficiencies the TGA would likely detect based on those documents;

(ii) pursuant to this request, Elia created a document entitled "Anticipated Deficiencies from Photocopied Documents" which identified 16 products in relation to which it was anticipated that the TGA would identify deficiencies in Pan's compliance with the GMP Code;

(m) otherwise does not admit the allegations in paragraph 40 of the FASC.

41 In answer to paragraph 41 of the FASC the Commonwealth:

(a) says that following 25 February 2003, Fraser with the assistance of Prestridge, Muir, Spence, Khoo and Grant, prepared drafts of an audit report relating to the findings of the incomplete audit which had been carried out on Pan on 24 and 25 February 2003;

(b) says that the draft audit reports prepared in relation to the incomplete audit which had been carried out on Pan on 24 and 25 February 2003 identified initially eight and then five critical deficiencies, being deficiencies which were assessed as being deficiencies which may produce, or may result in a significant risk of producing, a product that is harmful to the user;

(c) says that of the 16 products identified by Elia in the document entitled "Anticipated Deficiencies from Photocopied Documents", 11 appeared in the draft audit reports referred to in subparagraph (b) above as instances of critical deficiencies;

(d) otherwise does not admit the allegations in paragraph 41 of the FASC.

42 In answer to paragraph 42 of the FASC the Commonwealth:

(a) admits that there was a meeting on 6 March 2003 between Slater, Maclachlan, Tribe, Prestridge, Brian Priestly, Steve Howells (**Howells**) and Eric McIntosh;

(b) otherwise does not admit the allegations in paragraph 42 of the FASC.

43 The Commonwealth denies the allegations in paragraph 43 of the FASC.

**Proposal by Tribe, Fraser and Gould to issue a notice of intention to suspend Pan's manufacturing licence**

44 In answer to paragraph 44 of the FASC, the Commonwealth:

(a) says that on 19 March 2003, at a meeting involving Maclachlan, Cesarin, Gould, Tribe, Fraser, Howells and Ms Terry Lee (the TGA Legal Officer) (**Lee**), Maclachlan and Cesarin stated that they disagreed with any proposal to take regulatory action against Pan prior to the completion of the GMP audit of Pan which had commenced on 24 and 25 February 2003;

(b) says that Maclachlan and Cesarin were delegates of the Secretary under sections 28, 30 and 40 of the TG Act and were, therefore, persons empowered to take regulatory action in relation to Pan;

(c) says that on 20 March 2003 Tribe, Gould and Fraser (by phone) convened a meeting known as a "Review Panel Meeting" to discuss the findings of the incomplete audit of Pan which had occurred on 24 and 25 February 2003;

(d) says that Tribe, Fraser and Gould agreed at the meeting that the incomplete audit of Pan on 24 and 25 February 2003 had revealed widespread problems at Pan of a critical nature, with five critical deficiencies identified;

(e) says that Tribe, Fraser and Gould proposed at the meeting that Pan should be sent a notice of intention to suspend its manufacturing licence with a copy of the audit report attached, but which should be reviewed by the Australian Government Solicitor (**AGS**) before being sent to Pan;

(f) says that none of Tribe, Fraser or Gould was the relevant delegate of the Secretary under section 41(2) of the TG Act for the purposes of making any decision with respect to revoking or suspending Pan's licence;

(g) otherwise does not admit the allegations in paragraph 44 of the FASC.

45 In answer to paragraph 45 of the FASC, the Commonwealth:

(a) says that on 21 March 2003 Fraser sent to Tribe by email:

(i) drafts of an audit report relating to the incomplete audit of Pan which had occurred on 24 and 25 February 2003;

(ii) a draft of a letter from Maclachlan to Brennan giving notice of an intention to suspend Pan's licence for a period of up to six months under sections 40(1)(b) and (c) of the TG Act;

(b) says that on 21 March 2003 Tribe forwarded the documents referred to in the subparagraph (a) above to Lee for advice and Lee forwarded those documents to Andras Markus of the AGS (**Markus**);

(c) says that on 23 March 2003, following the receipt of Pan's letter of 19 March 2003 providing a further response to the Travacalm Audit Report, Tribe sought Lee's advice as to whether any notice of intention to suspend Pan's licence should be issued or whether it should be delayed to await the completion of the GMP audit of Pan which had commenced on 24 and 25 February 2003 and consideration of Pan's response to the Travacalm Audit Report of 19 March 2003;

(d) says that on 24 March 2003 Lee responded to Tribe advising that it was necessary to consider any material Pan has provided and foreshadowed obtaining further advice from Markus;

(e) says that on 24 March 2003 Markus advised Lee to the effect that:

(i) the immediate issue was whether the relevant delegate of the Secretary (Maclachlan) was of the view that the evidence available to her was sufficient to support a decision proposed by Tribe, Fraser and Gould, namely issuing a notice of intention to suspend Pan's licence;

(ii) it was possible that the delegate considered that she did not have evidence at that stage to make that decision and that she would prefer to

have the audit completed so that she had as much relevant information before her as possible;

(iii) it would be surprising if it were not considered necessary or appropriate to complete the truncated audit of Pan which had commenced on 24 and 25 February 2003 before taking any regulatory action in relation to Pan or its manufacturing processes;

(f) repeats paragraph 44(a) and (b) above;

(g) otherwise does not admit the allegations in paragraph 45 of the FASC.

46 In answer to paragraph 46 of the FASC, the Commonwealth:

(a) repeats paragraphs 44 and 45 above;

(b) denies that there had been any decision to suspend Pan's licence with 28 days notice;

(c) denies that there was any occasion to inform Pan of any decision to suspend Pan's licence with 28 days notice;

(d) otherwise does not admit the allegations in paragraph 46 of the FASC.

47 In answer to paragraph 47 of the FASC, the Commonwealth:

(a) admits that the documents referred to in paragraph 45(a) above were not sent to Pan;

(b) repeats paragraphs 44 and 46 above;

(c) denies that there was any occasion to send Pan the documents referred to in paragraph 45(a) above;

(d) otherwise does not admit the allegations in paragraph 47 of the FASC.

**Decision to complete audit of Pan commenced in February 2003**

48 In answer to paragraph 48 of the FASC, the Commonwealth:

(a) says that on 26 March 2003 a meeting between Maclachlan, Tribe, Gould and Lee occurred;

(b) says that at that meeting, Lee relayed to Maclachlan, Tribe and Gould the substance of the advice she had received from Markus on 24 March 2003;

(c) says that it was agreed at that meeting that:

(i) the audit of Pan that commenced on 24 and 25 February 2003 would be completed by conducting a further 5 days of auditing at Pan;

(ii) the relevant delegates of the Secretary would then make a decision, based on the findings of the completed audit of Pan, about whether and, if so, what regulatory action would be taken in relation to Pan;

(d) says that on 27 March 2003:

(i) Lee informed Markus of the intention to carry out a further 5 days of auditing at Pan in order to complete the audit of Pan commenced on 24 and 25 February 2003 and, on the basis of the findings of the completed audit, make a decision as to whether and, if so, what regulatory action would be taken in relation to Pan;

(ii) Markus informed Lee that he had no concerns with that approach and that it was not necessary to send to Pan a copy of the draft audit report in relation to the incomplete audit of Pan which had commenced on 24 and 25 February 2003;

(e) otherwise denies the allegations in paragraph 48 of the FASC.

**Continuation of GMP audit of Pan in April 2003**

49 In answer to paragraph 49 of the FASC, the Commonwealth:

(a) says that on 7 April 2003 Fraser, Prestridge and Milic attended at the premises of Pan in order to complete the audit of Pan which had commenced on 24 and 25 February 2003;

(b) says that Selim stated to Fraser upon or soon after his arrival at Pan that:

(i) he did not want the audit to occur;

(ii) Slater had agreed to postpone the audit;

(c) says that the statement of Selim's referred to in (b)(ii) above was false;

(d) says that, after Fraser conferred with Gould and Maclachlan, Fraser insisted that the audit of Pan proceed and that it did proceed;

(e) says that on 7 April 2003 Fraser was approached by Elia who asked to speak with him in confidence at a place away from Pan's premises during which meeting he would provide Fraser with information concerning practices that were going on within Pan and were of concern to him on condition that he maintain Elia's anonymity;

(f) says that on 8 April 2003 Spence and Paul Sidhu (an auditor within the TGA) (**Sidhu**) joined the audit of Pan and on 11 April Khoo joined the audit of Pan;

(g) says that on 9 April 2003 Fraser met with Elia for approximately 30 – 40 minutes and Elia advised Fraser to the effect that there were some very serious breaches of GMP going on at Pan including:

(i) batches of product were being released without authorisation for release because employees of Pan knew that there were quality problems with the product;

(ii) Brennan frequently instructed employees, including but not limited to Jain, to manipulate test results for products to change out of specification results to within specification;

(iii) Brennan had fabricated test results for vitamin A on certain batches of cod liver oil;

(iv) raw materials were frequently not tested or the results of testing were fabricated and this was approved by Brennan and Selim;

(v) finished products were being released for supply to customers prior to testing being completed at the direction of Brennan and/or Selim;

(vi) where Pan was making a product and had insufficient quantity of active materials, it would simply make up the difference using inactive material or bulking agent;

(vii) machinery was not cleaned between batches because it would mean the time available for production would be restricted;

(h) says that the GMP audit of Pan was completed on 14 April 2003;

(i) says that on 14 April 2003:

(i) Fraser and Milic conducted an exit interview with Selim and informed him that the audit had identified a large number of deficiencies, including numerous items rated as critical, and summarised those deficiencies;

(ii) Selim stated that he regarded the matters raised by Fraser and Milic as marginal;

(j) otherwise does not admit the allegations in paragraph 49 of the FASC.

50 In answer to paragraph 50 of the FASC, the Commonwealth:

(a) admits that the GMP audit of Pan carried out in February and April 2003 was an unannounced audit;

(b) says that pursuant to SOP 401.8, an unannounced GMP audit was appropriate where it is believed that the true extent of GMP compliance cannot otherwise be assessed because:

(i) there were good grounds for suspecting gross lapses in GMP compliance;

(ii) they would be covered up if the licence holder had received advance notice;

(c) repeats paragraph 30(c) above;

(d) says that, in the premises, it was appropriate that the GMP audit of Pan carried out in February and April 2003 was an unannounced audit;

(e) otherwise does not admit the allegations in paragraph 50 of the FASC.

**Briefing to the Parliamentary Secretary of 11 April 2003**

51 In answer to paragraph 51 of the FASC, the Commonwealth:

(a) repeats paragraphs 39(h) and (i) above;

(b) says that paragraph 51 of the FASC is not an accurate characterisation of the documents referred to in paragraphs 39(h) and (i);

(c) relies on the documents referred to in paragraphs 39(h) and (i) above for their full force and effect;

(d) otherwise does not admit the allegations in paragraph 51 of the FASC.

**Preparation of the audit report from the February and April 2003 audit of Pan**

52 In answer to paragraph 52 of the FASC, the Commonwealth:

(a) repeats paragraph 41(a) above;

(b) says that from 14 April 2003 until 27 April 2003 Fraser, with the assistance of Prestridge, Milic, Spence, Sidhu and Khoo, continued drafting the audit report for

the GMP audit of Pan in order to incorporate into that report the findings of the continuation of that audit on 7 to 14 April 2003;and

(c) otherwise does not admit the allegations in paragraph 52 of the FASC.

53 In answer to paragraph 53 of the FASC, the Commonwealth:

(a) repeats paragraph 39(l) above;

(b) otherwise does not admit the allegations in paragraph 53 of the FASC.

**The Expert Advisory Group**

54 In answer to paragraph 54 of the FASC, the Commonwealth:

(a) repeats paragraph 39(j) above;

(b) says that on or about 15 April 2003 Slater together with Maclachlan, McEwen and Dr Fiona Cumming, the Principal Scientific Adviser for the Trans Tasman Group in the TGA (**Cumming**), decided to organise an expert committee in order to give advice in connection with any regulatory action to be taken in relation to Pan;

(c) says that the expert committee was known as an Expert Advisory Group (**EAG**) and was to consist of persons who were members of other expert committees convened under the TG Act, namely the Medicines Evaluation Committee (**MEC**), the Complementary Medicines Evaluation Committee (**CMEC**) and the Adverse Drug Reactions Advisory Committee (**ADRAC**);

(d) says that the purposes of the EAG was to provide advice to the relevant delegates of the Secretary under the TG Act (Maclachlan and Cesarin) about the public health risks associated with the findings of the GMP audit carried out on Pan in February and April 2003;

(e) says that on or about 15 April 2003 Lee sought and obtained Markus's advice in relation to the proposal to establish the EAG and Markus advised to the effect that the establishment of an advisory committee was proper so long as any regulatory decision was taken by the relevant delegates of the Secretary under the TG Act;

(f) says that the membership of the EAG was as follows:

(i) Professor Gillian Shenfield, a clinical pharmacologist and member of the MEC and CMEC;

(ii) Professor Stephen Myers, a medical practitioner, naturopath, clinical pharmacologist Director of the Australian Centre for Complementary Medicines and member of the CMEC;

(iii) Dr Richard Whiting, a geriatrician and general practitioner, and member of the MEC;

(iv) Professor Bill Webster, a toxicologist and member of the CMEC and ADRAC;

(v) Professor Henry Kilham, a paediatrician and member of the MEC;

(vi) Associate Professor Heather Yeatman, a nutritionist and member of the CMEC;

(g) the EAG met at the Qantas Club at Sydney Airport on 23 April 2003 (**EAG Meeting**);

(h) otherwise does not admit the allegations in paragraph 54 of the FASC.

55 In answer to paragraph 55 of the FASC, the Commonwealth:

(a) admits that Maclachlan, Fraser and McEwen attended the EAG Meeting;

(b) says that Karl Skewes, an employee within the TGA also attended the EAG Meeting;

(c) otherwise does not admit the allegations in paragraph 55 of the FASC.

56 In answer to paragraph 56 of the FASC, the Commonwealth:

(a) says that the terms of reference of the EAG and the materials with which the EAG was briefed were prepared principally by Cumming in consultation with Maclachlan and Slater;

(b) says that on 17 April 2003 Lee sent to Markus by email copies of the proposed terms of reference of the EAG and materials with which the EAG was proposed to be briefed for his advice and Markus approved the content of those documents;

(c) otherwise does not admit the allegations in paragraph 56 of the FASC.

57 In answer to paragraph 57 of the FASC, the Commonwealth:

(a) says that following its meeting of 23 April 2003, the EAG issued a report (**EAG Report**) in which the EAG advised to the effect that:

(i) the multiple failures of GMP identified in the report of the audit conducted on Pan in February and April 2003, in the opinion of the EAG, created risks of death, serious illness or serious injury;

(ii) specifically the issues identified included;

(A) misidentification (mix-up) of raw materials, especially herbal materials, which could lead to severe organ damage, including renal and hepatic damage;

(B) cross contamination or substitution of ingredients due to inadequate operating procedures and poor compliance with existing procedures, which could lead to severe allergic reactions including anaphylaxis;

(C) microbiological contamination through poor raw material sourcing and handling, poor cleaning practices and inadequate operating procedures which could lead to infections;

(iii) the risk will increase over time;

(iv) the risk could be realised at any time;

(v) the EAG lacked confidence in the quality of any products manufactured by Pan and advised that poor quality products have an increased risk of failure in both safety and efficacy;

(vi) the EAG recommended that Pan should be subject to significant remediation and recommended that Pan's manufacturing licence should be suspended immediately for the protection of the community's health and safety;

(b) says that the advice of the EAG was, in substance, to the effect that a failure to take regulatory action in relation to Pan and the therapeutic goods it manufactured would create an imminent risk of death, serious illness or serious injury;

(c) says that on or about 23 April 2003 or 24 April 2003 Markus advised Lee to the effect of subparagraph (b) above and Lee passed that advice, together with her own advice to that effect, on to Maclachlan and Cesarin;

(d) otherwise denies the allegations in paragraph 57 of the FASC.

58 In answer to paragraph 58 of the FASC, the Commonwealth:

(a) says that on the evening of 23 April 2003 Slater, Maclachlan, Gould, McEwen and Cumming attended a meeting at the TGA's offices in Canberra;

(b) says that at that meeting the following matters were discussed:

(i) the conclusions of the EAG pleaded in paragraph 57 above;

(ii) what regulatory decisions under the TG Act might be appropriate in the light of the advice of the EAG pleaded in paragraph 57 above;

(iii) what logistical planning was necessary in order to implement any regulatory decisions taken in relation to Pan;

(c) says that no final decision was made at the meeting on the evening 23 April 2003 as to any regulatory decision to be taken under the TG Act in relation to Pan and the therapeutic goods manufactured by Pan;

(d) otherwise denies the allegations in paragraph 58 of the FASC.

59 In answer to paragraph 59 of the FASC, the Commonwealth:

(a) repeats paragraph 58 above;

(b) otherwise denies the allegations in paragraph 59 of the FASC.

60 In answer to paragraph 60 of the FASC, the Commonwealth:

(a) says Cesarin took annual leave from 22 April 2003 to 24 April 2003;

(b) notwithstanding (a) above, Cesarin attended the offices of the TGA on 24 April 2003 and read:

(i) a draft of the report of the GMP audit of Pan conducted in February and April 2003;

(ii) a draft of the EAG Report;

(c) otherwise denies the allegations in paragraph 60 of the FASC.

61 In answer to paragraph 61 of the FASC, the Commonwealth:

(a) says that from 24 April 2003 Slater was sent and considered the draft press releases and "Frequently Asked Questions" documents relating to the possible regulatory decisions to be taken under the TG Act in relation to Pan and the therapeutic goods manufactured by Pan;

(b) otherwise denies the allegations in paragraph 61 of the FASC.

62 In answer to paragraph 62 of the FASC, the Commonwealth:

(a) repeats paragraph 52 above;

(b) otherwise does not admit the allegations in paragraph 62 of the FASC.

**Regulatory decisions taken in relation to Pan and the therapeutic goods manufactured by Pan**

63 In answer to paragraph 63 of the FASC, the Commonwealth:

(a) says that on 28 April 2003 Cesarin signed two letters addressed to Pan;

(b) the first of the letters referred to in subparagraph (a) above informed Pan to the effect that *inter alia*:

(i) as delegate of the Secretary, he had decided pursuant to section 30(1)(a) of the TG Act to cancel the listing or registration on the ARTG of all the

medicines listed in the attachment to that letter, being medicines of which Pan was the manufacturer and sponsor on the ARTG;

(ii) the cancellation was effective immediately because Cesarin was of the belief that the failure to do so would create an imminent risk of death, serious illness or serious injury;

(iii) Cesarin was directing Pan to take steps to recover all the goods listed in the attachment to that letter that had been manufactured and supplied by Pan after 1 May 2002;

(iv) Cesarin's decision was an "initial decision" within the meaning of section 60 of the TG Act which meant that if a person's interests were affected by the decision that person could seek reconsideration by the Minister and, in the event of dissatisfaction with the Minister's decision, appeal to the Administrative Appeals Tribunal for a review of the Minister's decision;

(c) the second of the letters referred to in subparagraph (a) above was to the same effect as the letter referred to in subparagraph (b), but:

(i) related to medicines listed on the ARTG for export only and of which Pan was the manufacturer and sponsor;

(ii) did not require Pan to take steps to recover the goods listed in the attachment to that letter;

(d) relies on the letters referred to in subparagraphs (b) and (c) above for their full force and effect;

(e) otherwise does not admit the allegations in paragraph 63 of the FASC.

64 In answer to paragraph 64 of the FASC, the Commonwealth:

(a) says that on 28 April 2003 Maclachlan, McEwen, Gould and Fraser attended a meeting with the Board of Pan at Pan's premises;

(b) otherwise does not admit the allegations in paragraph 64 of the FASC.

65 In answer to paragraph 65 of the FASC, the Commonwealth:

(a) says that at the meeting referred to in paragraph 64 above:

(i) a copy of the audit report for the GMP audit of Pan which had occurred in February and April 2003 (**Pan Audit Report**) was provided to Pan's Board;

(ii) Fraser summarised the findings of the Pan Audit Report;

(iii) Maclachlan informed Pan's Board:

(A) to the effect that she had decided, as delegate of the Secretary under section 41 of the TG Act, to suspend Pan's licence to manufacture therapeutic goods for a period of six months;

(B) to the effect that the suspension of Pan's licence to manufacture therapeutic goods would take effect immediately because she was of the view that there was an imminent risk of death, serious illness or serious injury with Pan being allowed to continue to manufacture therapeutic goods;

(C) to the effect that she had decided, as delegate of the Secretary under section 40(2) of the TG Act, to impose two new conditions on Pan's licence to manufacture therapeutic goods requiring Pan to *inter alia* take action during the period of its suspension to ensure its compliance with the manufacturing principles made under section 36 of the TG Act and allow the TGA full access to establish the extent of the GMP issues that needed to be addressed by Pan before the suspension was removed;

(D) of the reasons for her decisions in (A), (B) and (C) above;

(iv) Maclachlan provided to Pan's Board a letter from her to Pan dated 28 April 2003 which *inter alia*:

(A) explained her decisions pleaded in subparagraph (a)(iii) above;

(B) explained her reasons for those decisions;

(C) informed Pan that her decision was an "initial decision" within the meaning of section 60 of the TG Act which meant that if a person's interests were affected by the decision that person could seek reconsideration by the Minister and, in the event of dissatisfaction with the Minister's decision, appeal to the Administrative Appeals Tribunal for a review of the Minister's decision;

(b) says that Maclachlan informed Pan's Board of Cesarin's decisions pleaded in paragraph 63 above;

(c) says that Maclachlan provided to Pan a copy of the letters of Cesarin to Pan referred to in paragraph 63 above;

(d) otherwise does not admit the allegations in paragraph 65 of the FASC.

66 In answer to paragraph 66 of the FASC, the Commonwealth:

(a) repeats paragraph 65(b) and (c) above;

(b) otherwise denies the allegations in paragraph 66 of the FASC.

67 In answer to paragraph 67 of the FASC, the Commonwealth:

(a) says that on 28 April 2003 Cesarin signed and caused to be sent letters to persons who were sponsors of products listed or registered on the ARTG of which Pan was a manufacturer;

(b) says that the letters sent by Cesarin to sponsors on 28 April 2003 took four forms as follows:

(i) a letter to sponsors of products listed or registered on the ARTG of which Pan was the sole or principal manufacturer of the medicine on the ARTG and where the medicines were approved for sale in Australia;

(ii) a letter to sponsors of products listed or registered on the ARTG of which Pan was one of a number of manufacturers of the medicine on the ARTG and where the medicines were approved for sale in Australia;

(iii) a letter to sponsors of products listed or registered on the ARTG of which Pan was the sole or principal manufacturer of the medicine on the ARTG and where the medicines were approved for export only;

(iv) a letter to sponsors of products listed or registered on the ARTG of which Pan was one of a number of manufacturers of the medicine on the ARTG and where the medicines were approved for export only;

(c) says that in the letters pleaded in subparagraphs (b)(i) and (ii) above, Cesarin:

(i) informed the sponsor that as delegate of the Secretary under section 28(3) of the TG Act he had decided to impose a condition on the listing or registration on the ARTG of the medicines listed in the attachment to that letter which stated that: "Any further supply of products manufactured by Pan Pharmaceuticals Ltd since 1 May 2002 must cease";

(ii) informed the sponsor that the imposition of the condition on the listing or registration on the ARTG of the medicines listed in the attachment to the letter referred to in subparagraph (i) above took effect from the date of the letter because Cesarin considered that the imposition of the condition was necessary to prevent imminent risk of death, serious illness or serious injury;

(iii) explained the reasons for his decision;

(iv) stated that his decision was an "initial decision" within the meaning of section 60 of the TG Act which meant that if a person's interests were affected by the decision that person could seek reconsideration by the Minister and, in the event of dissatisfaction with the Minister's decision,

appeal to the Administrative Appeals Tribunal for a review of the Minister's decision;

(v) stated that given the problems identified with Pan and the seriousness of the safety concerns associated with products manufactured by Pan, the sponsor was strongly encouraged to immediately initiate a voluntary safety related consumer level recall of all batches of product manufactured by Pan since 1 May 2002;

(d) says that in the letters pleaded in subparagraph (b)(iii) and (iv) above, Cesarin:

(i) included statements to the effect set out in subparagraph (c)(i) to (iv) above; but

(ii) did not include any statement to the effect set out in subparagraph (c)(v) above;

(e) relies on the letters referred to in subparagraph (a) above for their full force and effect;

(f) otherwise does not admit the allegations in paragraph 67 of the FASC.

**Media releases in relation to regulatory actions taken in relation to Pan and the therapeutic goods it manufactured**

68 In answer to paragraph 68 of the FASC, the Commonwealth:

(a) says that on 28 April 2003 there was published a "Media Release" under the letterhead of the TGA entitled "National Medicines Regulator Suspends Drug Company's Manufacturing Licence";

(b) says that on 28 April 2003 the Parliamentary Secretary issued a "Media Release" entitled "Federal Government to Strengthen Pharmaceutical Laws";

(c) says that on 29 April 2003 there was published a "Media Release" under the letterhead of the TGA entitled "Pan Pharmaceuticals Limited Recall Update";

(d) says that on 30 April 2003 there was published on the TGA website an article entitled "Urgent Medical Recall – Products manufactured by Pan Pharmaceuticals Limited and supplied by various sponsors and distributors";

(e) says that on 30 April 2003 there was published on the TGA website an article entitled "Urgent Medical Recall – various products manufactured and supplied by Pan Pharmaceuticals Limited";

(f) says that on 1 May 2003 there was published a "Media Release" under the letterhead of the TGA entitled "TGA Issues Final List of Pan Products";

(g) says that on 2 May 2003 there was published a "Media Release" under the letterhead of the TGA entitled "Allegron 25mg subject to Pan Pharmaceuticals Recall";

(h) says that on 2 May 2003 the Parliamentary Secretary issued a "Media Release" entitled "Pan Recall List to be Published in Regional Newspapers";

(i) says that on 5 May 2003 there was published a "Media Release" under the letterhead of the TGA entitled "More Names to be added to TGA Recall List";

(j) says that on 28 April 2003 there was published on the TGA website an article entitled "National medicines regulator suspends drug company's manufacturing licence – Questions and Answers for Consumers";

(k) says that on 29 April 2003 there was published on the TGA website an article entitled "Pan Pharmaceuticals Limited – regulatory Action and Product Recall Information";

(l) relies on the documents pleaded in subparagraphs (a) to (k) above for their full force and effect;

(m) otherwise does not admit the allegations in paragraph 68 of the FASC.

**Pan placed into administration and liquidation, and Pan's licence restored**

69 In answer to paragraph 69 of the FASC, the Commonwealth:

(a) says that trading in Pan's shares was suspended on the Australian Stock Exchange on 30 April 2003;

(b) otherwise admits the allegations in paragraph 69 of the FASC;

(c) says further that in May 2003 Pan retained a team of consultants led by Rodney Unsworth (**Unsworth**) for the purposes of identifying and undertaking the remedial action of Pan's operations necessary to enable the restoration of Pan's licence to manufacture therapeutic goods;

(d) says further that on 26 May 2003 Unsworth together with the acting CEO of Pan, Colin Henson, and the administrator of Pan, Tony McGrath, gave a presentation to Maclachlan and Gould as to the remedial tasks intended to be undertaken at Pan in order to enable the restoration of Pan's licence to manufacture therapeutic goods;

(e) says further that on 22 – 24 July 2003 an audit team led by Andrew Lattimore, a GMP auditor of the TGA (**Lattimore**), undertook a GMP audit of Pan in order to assess whether the remedial work undertaken at Pan to that date enabled the restoration of Pan's licence to manufacture therapeutic goods;

(f) says further that on 8 August 2003 Lattimore issued an audit report relating to the audit of 22 – 24 July 2003 which stated to the effect that:

(i) while a large amount of work had been completed, significant work was still required for Pan to achieve an acceptable level of GMP compliance;

(ii) Pan was not compliant with the GMP Code and that reinstatement of Pan's licence to manufacture therapeutic goods could not be recommended; but

(iii) if the current level of activity continued Pan may reach an acceptable level of compliance within a relatively short time frame;

(g) says further that on 27 – 29 August 2003 an audit team led by Lattimore conducted a further GMP audit of Pan in order to assess whether the remedial work undertaken at Pan to that date enabled the restoration of Pan's licence to manufacture therapeutic goods;

(h) says further that on 26 September 2003 Lattimore issued an audit report relating to the audit of 27 – 29 August 2003 which stated to the effect that:

(i) while a large amount of work had been completed since the 22 – 24 July 2003 audit, work was still required to achieve an acceptable level of GMP compliance;

(ii) Pan was not compliant with the GMP Code and that reinstatement of Pan's licence to manufacture therapeutic goods could not be recommended; but

(iii) if the current level of activity continued, Pan may reach an acceptable level of compliance within a relatively short time frame;

(i) says further that on 29 September 2003 an audit team led by Lattimore conducted a further GMP audit of Pan in order to assess whether the remedial work undertaken at Pan to that date enabled the restoration of Pan's licence to manufacture therapeutic goods;

(j) says further that on 1 October 2003 Lattimore issued an audit report relating to the audit of 29 September 2003 which concluded that Pan was compliant with the GMP Code and that reinstatement of Pan's licence to manufacture therapeutic goods, namely listable soft gelatin capsules, could be recommended;

(k) says further that by letter dated 5 November 2003 Maclachlan revoked the suspension of Pan's licence and re-instated Pan's licence to manufacture therapeutic goods subject to the conditions and restrictions referred to in that letter.

## D. THE ALLEGED "NEW STRATEGY"

**There was no "New Strategy"**

70 In answer to paragraph 70 of the FASC, the Commonwealth:

(a) repeats paragraph 48 above;

(b) otherwise denies the allegations in paragraph 70 of the FASC.

71 In answer to paragraph 71 of the FASC, the Commonwealth:

(a) repeats paragraphs 39 to 62, 64 to 66, and 68 above;

(b) otherwise denies the allegations in paragraph 71 of the FASC.

72 The Commonwealth denies the allegations in paragraph 72 of the FASC.

73 In answer to paragraph 73 of the FASC, the Commonwealth:

(a) repeats paragraphs 63 and 67 above;

(b) otherwise denies the allegations in paragraph 73 of the FASC.

**Alleged malicious beliefs of Slater, Maclachlan, Tribe, Fraser and Cesarin**

74 In answer to paragraph 74 of the FASC, the Commonwealth:

(a) makes no admissions as to the knowledge of any other respondent;

***"Medicaps" prosecution of Pan Labs was defeated on "technicality":***

(b) says that in August 1996 Pan Labs was convicted in the District Court of New South Wales of 13 offences under section 20 of the TG Act relating to the supply of Evening Primrose Oil (**EPO**) imported from a manufacturer in Thailand known as Medicap Ltd which product was not a listed good on the ARTG, or an exempt good or a good the subject of an approval under section 19 of the TG Act;

(c) says that:

(i) at trial Pan Lab's defence was directed towards showing that Pan was not the sponsor of the therapeutic good and that EPO was a food and not a therapeutic good;

(ii) Judge Nield described Pan Lab's defence as "fanciful"; and

(iii) Judge Nield concluded that some of the offences of which Pan Labs had been convicted had been committed knowingly and intentionally such as to amount to deliberate and flagrant breaches of the TG Act;

(d) says that on 2 July 1997 the New South Wales Court of Criminal Appeal allowed Pan Lab's appeal, quashed the conviction and ordered a re-trial;

(e) says that the basis of the Court of Criminal Appeal's decision was that Judge Nield had wrongly concluded that Pan Labs bore the onus of proving under section 20 of the TG Act that EPO was not a registered or listed good on the ARTG in relation to Pan Labs;

(f) says that at trial Pan Labs made no attempt to prove that EPO was not a registered or listed good in relation to Pan Labs;

(g) says that, by reason of the matters in subparagraphs (c) to (f) the prosecution of Pan Labs referred to subparagraph (b) was defeated on a technical rather than a substantive basis;

***Pan Labs was placed into voluntary liquidation to avert continuation of Medicaps prosecution:***

(h) says that on 31 July 1998:

(i) the Commonwealth Director of Public Prosecutions (**CDPP**) presented to the District Court of New South Wales an indictment charging Pan Labs with the same 13 offences under section 20 of the TG Act of which it had been convicted on 5 August 1999;

(ii) the matter was listed for re-trial for two weeks commencing 30 November 1998;

(i) says that, following the commencement by Pan Labs of proceedings in the High Court of Australia challenging the constitutional validity of the TG Act, the re-trial due to commence on 30 November 1998 was vacated and listed for two weeks to commence on 28 June 1999;

(j) says that on 19 February 1999 Kirby J remitted the proceedings commenced by Pan Labs in the High Court of Australia to the District Court of New South Wales to be heard together with the re-trial of Pan Labs due to commence on 28 June 1999;

(k) says that on 26 March 1999 Pan Labs and Selim received advice from senior and junior counsel to the effect that Pan Labs being placed into voluntary liquidation could be anticipated to be a disincentive to the CDPP proceeding with the re-trial of Pan Labs due to commence on 28 June 1999;

(l) says that on 12 May 1999 Selim filed with the Australian Securities Commission a form containing a resolution that Pan Labs be voluntarily wound up and a liquidator be appointed;

(m) says that Pan Labs was placed into voluntary liquidation to seek to avert continuation of the prosecution of Pan Labs of the charges referred to subparagraph (h);

(n) says that on 14 May 1999 Pan Lab's solicitor wrote to the CDPP advising that a liquidator had been appointed to Pan Labs and stating to the effect that he assumed that the Crown would not be proceeding against Pan Labs in relation to the charges under the TG Act;

(o) says that in August 1999 the CDPP discontinued the prosecution of Pan Labs;

(p) repeats paragraph 13(c) above;

***Selim directed destruction of data before and during Travacalm audit:***

(q) repeats paragraph 13(c) and paragraphs 33(aa), (bb), (cc) and (gg) above and says that by reason of the matters set out in those paragraphs Selim and Brennan directed destruction of data before and during the Travacalm Audit;

***Pan's position that Jain was solely responsible for data manipulation had no proper basis:***

(r) says that the analyst's worksheet containing the manipulated uniformity of content test results for Travacalm batch 78586 is not in Jain's handwriting but is in the handwriting of Fernandez;

(s) says that by reason of the matters set out in paragraphs 33(f) to (j) and 36(c) above and subparagraph (r), Pan's statements to the TGA that Jain was solely responsible for the data manipulation in relation to Travacalm and that the data manipulation carried out by Jain in relation to Travacalm was an isolated incident had no proper basis and were false;

***Jain's continued employment by Pan after Travacalm Audit Report:***

(t) repeats paragraph 33(hh) and (ii) above;

(u) says that:

(i) on 10 February 2003 Brennan and Elia signed a letter to Jain stating that his action of manipulating the results of uniformity of content testing in relation to Travacalm was considered "gross negligence" and any further actions of gross negligence would result in his instant dismissal;

(ii) on 13 February 2003 Fraser and Prestridge observed Jain still working in the laboratory at Pan conducting analysis as pleaded in paragraphs 36(e)(i) and 38 above;

(iii) on 17 February 2003 the TGA wrote to Pan and expressed its concern about Jain's continued presence in Pan's laboratory despite being the person identified by Pan as responsible for sabotage in relation to Travacalm as pleaded in paragraph 36(e) above;

(iv) on 21 February 2003 Jain resigned from Pan on the basis that "[d]ue to unavoidable circumstances I cannot continue in my job";

***Pan had committed criminal offences:***

(v) repeats paragraph 33(a) to (cc) and 36(c) says that by reason of those matters:

(i) Pan was guilty of 19 offences of supplying counterfeit therapeutic goods contrary to section 42E of the TG Act, 10 of which related to manipulation of test data in relation to Travacalm and incorrect labelling of Travacalm, and 9 of which related to the manipulation of test results in relation to other products;

(ii) Pan was guilty of 5 offences of negligently causing grievous bodily harm contrary to section 54 of the *Crimes Act 1900* (NSW);

(iii) Pan was convicted of the offences referred to in subparagraphs (i) and (ii) on 28 November 2005.

***Pan or Selim had attempted to obstruct or hinder the audit of Pan in February 2003:***

(w) repeats paragraphs 38(b), 40(g) - (i), and 49(b) and (c) above;

(x) otherwise does not admit the allegations in paragraph 74 of the FASC.

75 The Commonwealth denies the allegations in paragraph 75 of the FASC.

## E. MISFEASANCE IN PUBLIC OFFICE

### Knowledge

76 In answer to paragraph 76 of the FASC, the Commonwealth:

(a) repeats paragraph 70 above;

(b) otherwise does not admit the allegations in paragraph 76 of the FASC.

### The Pan Suspension

77 The Commonwealth denies the allegations in paragraph 77 of the FASC.

78 The Commonwealth admits the allegations in paragraph 78 of the FASC.

79 The Commonwealth admits the allegations in paragraph 79 of the FASC.

80 In answer to paragraph 80 of the FASC, the Commonwealth:

(i) says that on 28 April 2003 Maclachlan as delegate of the Secretary:

(A) decided under section 41(2) of the TG Act to suspend Pan's licence to manufacture therapeutic goods for a period of six months (the **Pan Suspension Decision**);

(B) formed the view that the failure to suspend Pan's licence immediately would create an imminent risk of death, serious illness or serious injury within the meaning of section 41(2) of the TG Act;

(C) decided under section 40(2) of the TG Act to impose two new conditions on Pan's licence to manufacture therapeutic goods requiring Pan to *inter alia* take action during the period of its suspension to ensure its compliance with the manufacturing principles made under section 36 of the TG Act and allow the TGA full access to establish the extent of the GMP issues that needed to be addressed by Pan before the suspension was removed (the **Pan Additional Conditions Decision**);

(ii) says that the Travacalm Audit Report, the Pan Audit Report and the EAG Report provided a reasonable and proper basis for the Pan Suspension Decision and the Pan Additional Conditions Decision;

(b) otherwise does not admit the allegations in paragraph 80 of the FASC.

81 The Commonwealth denies the allegations in paragraph 81 of the FASC.

82 The Commonwealth denies the allegations in paragraph 82 of the FASC.

83 The Commonwealth denies the allegations in paragraph 83 of the FASC.

84 The Commonwealth denies the allegations in paragraph 84 of the FASC.

85 In answer to paragraph 85 of the FASC, the Commonwealth:

(a) denies the allegations in paragraph 85 of the FASC;

(b) says further that:

(i) it is an essential element of the tort of misfeasance in public office that the claimant show that he, she or it was a member of the public or one of the members of the public to whom the holder of the public office owed a duty to exercise the power legitimately;

(ii) Maclachlan did not owe Pharm-a-care or the "Injured Persons" (as defined in the FASC) a duty to exercise the power in section 41 of the TG Act legitimately;

(c) says further that:

(i) the tort of misfeasance in public office is only actionable by persons who are at the time of the relevant exercise of power identified or part of an identifiable class and are directly affected by the impugned exercise of power;

(ii) Pharm-a-care and the "Injured Persons" (as defined in the FASC) were not:

(A) identified or did not form an identifiable class at the time of Maclachlan's decision to suspend Pan's licence to manufacture therapeutic goods with immediate effect under section 41 of the TG Act;

(B) were not directly affected by Maclachlan's decision to suspend Pan's licence to manufacture therapeutic goods with immediate effect under section 41 of the TG Act.

**The Pan Cancellation**

86 The Commonwealth denies the allegations in paragraph 86 of the FASC.

87 The Commonwealth admits the allegations in paragraph 87 of the FASC.

88 The Commonwealth admits the allegations in paragraph 88 of the FASC.

89 In answer to paragraph 89 of the FASC, the Commonwealth:

(i) says that on 28 April 2003:

(A) it appeared to Cesarin as delegate of the Secretary that the failure to cancel the registration or listing on the ARTG of all the medicines of which Pan was listed as a manufacturer and sponsor would create an imminent risk of death, serious illness or serious injury;

(B) Cesarin as delegate of the Secretary decided pursuant to section 30(1)(a) of the TG Act to cancel the registration or listing on the ARTG of all the medicines of which Pan was listed as a manufacturer and sponsor (the **Pan Cancellation Decision**);

(C) Cesarin decided to direct Pan to take steps to recover all the goods listed in the attachment to that letter that had been manufactured and supplied by Pan after 1 May 2002 (the **Pan Recall Direction**);

(ii) says that the Travacalm Audit Report, the Pan Audit Report and the EAG Report provided a reasonable and proper basis for the Pan Cancellation Decision and the Pan Recall Direction;

(b) otherwise does not admit the allegations in paragraph 89 of the FASC.

90 The Commonwealth denies the allegations in paragraph 90 of the FASC.

91 The Commonwealth denies the allegations in paragraph 91 of the FASC.

92 The Commonwealth denies the allegations in paragraph 92 of the FASC.

93 In answer to paragraph 93 of the FASC, the Commonwealth:

(a) denies the allegations in paragraph 93 of the FASC;

(b) repeats paragraph 85(b)(i) above and says further that Cesarin did not owe Pharm-a-care or the "Injured Persons" (as defined in the FASC) a duty to exercise the power in section 30(1) of the TG Act legitimately;

(c) repeats paragraph 85(c)(i) above and says further that Pharm-a-care and the "Injured Persons" (as defined in the FASC) were not:

(i) identified or did not form an identifiable class at the time of Cesarin's decision pursuant to section 30(1)(a) of the TG Act to cancel from the ARTG all the medicines listed in the attachments to his letters of 28 April 2003 to Selim;

(ii) were not directly affected by Cesarin's decision pursuant to section 30(1)(a) of the TG Act to cancel from the ARTG all the medicines listed in the attachments to his letters of 28 April 2003 to Selim.

**The Pan Recall**

94 The Commonwealth denies the allegations in paragraph 94 of the FASC.

95 The Commonwealth admits the allegations in paragraph 95 of the FASC.

96 The Commonwealth admits the allegations in paragraph 96 of the FASC.

97 In answer to paragraph 97 of the FASC, the Commonwealth:

(a) says that Cesarin's decision to require Pan to take steps to immediately recover all the medicines listed in the attachment to his letter of 28 April 2003 to Pan referred to in paragraph 63(b) above was consequential upon his decision to cancel from the ARTG all the medicines listed in the attachment to that letter;

(b) otherwise does not admit the allegations in paragraph 97 of the FASC.

98 The Commonwealth denies the allegations in paragraph 98 of the FASC.

99 The Commonwealth denies the allegations in paragraph 99 of the FASC.

100 The Commonwealth denies the allegations in paragraph 100 of the FASC.

101 The Commonwealth denies the allegations in paragraph 101 of the FASC.

102 The Commonwealth denies the allegations in paragraph 102 of the FASC.

103 In answer to paragraph 103 of the FASC, the Commonwealth:

(a) denies the allegations in paragraph 103 of the FASC;

(b) repeats paragraph 85(b)(i) above and says further that Cesarin did not owe Pharm-a-care or the "Injured Persons" (as defined in the FASC) a duty to exercise the power in section 30(6) of the TG Act legitimately;

(c) repeats paragraph 85(c)(i) above and says further that Pharm-a-care and the "Injured Persons" (as defined in the FASC) were not:

(i) identified or did not form an identifiable class at the time of Cesarin's decision pursuant to section 30(6) of the TG Act to require Pan to take steps to immediately recover all the medicines listed in the attachment to his letter of 28 April 2003 to Pan referred to in paragraph 63(b) above;

(ii) were not directly affected by Cesarin's decision pursuant to section 30(6) of the TG Act to require Pan to take steps to immediately recover all the medicines listed in the attachment to his letter of 28 April 2003 to Pan referred to in paragraph 63(b) above.

**The Sponsor Prohibition on Supply**

104 The Commonwealth denies the allegations in paragraph 104 of the FASC.

105 The Commonwealth admits the allegations in paragraph 105 of the FASC.

106 The Commonwealth admits the allegations in paragraph 106 of the FASC.

107 In answer to paragraph 107 of the FASC, the Commonwealth:

(a) says that Cesarin's decision under section 28(3) of the TG Act to impose on the listing or registration on the ARTG of goods manufactured by Pan a condition to the effect that any further supply of products manufactured by Pan after 1 May 2002 must cease took immediate effect because he considered that that action was necessary to prevent imminent risk of death, serious illness or serious injury;

(b) says that there was a reasonable and proper basis for Cesarin's decision;

**Particulars**

(i) The material referred to in Cesarin's letters of 28 April 2003 referred to in paragraph 67 above.

(ii) Further particulars may be provided prior to trial.

(c) otherwise does not admit the allegations in paragraph 107 of the FASC.

108 The Commonwealth denies the allegations in paragraph 108 of the FASC.

109 The Commonwealth denies the allegations in paragraph 109 of the FASC.

110 The Commonwealth denies the allegations in paragraph 110 of the FASC.

111 In answer to paragraph 111 of the FASC, the Commonwealth:

(a) denies the allegations in paragraph 111 of the FASC;

(b) repeats paragraph 85(b)(i) above and says further that Cesarin did not owe "Pan Suppliers" or "Pan Distributors" (as defined in the FASC) a duty to exercise the power in section 28(2) of the TG Act legitimately;

(c) repeats paragraph 85(c)(i) above and says further that "Pan Suppliers" and/or "Pan Distributors" (as defined in the FASC) were not:

(i) identified or did not form an identifiable class at the time of Cesarin's decision to impose under section 28(2) of the TG Act on the listing or registration on the ARTG of goods manufactured by Pan a condition to the effect that any further supply of products manufactured by Pan after 1 May 2002 must cease;

(ii) were not directly affected by Cesarin's decision under section 28(2) of the TG Act to impose that condition;

(d) says that:

(i) on 23 July 2003 Pharm-a-care (by its then solicitors Ebsworth & Ebsworth) sought review by the Minister under section 60 of the TG Act of Cesarin's decision referred to in paragraph 67 above to impose a condition on the registration or listing of goods of which it was the sponsor

and Pan was a manufacturer preventing the further supply of goods manufactured by Pan after 1 May 2002;

(ii) says that on 29 September 2003 the delegate of the Minister (Dr Leonie Hunt) wrote to Pharm-a-care's then solicitors affirming the decision of Cesarin to impose a condition on the registration or listing of goods of which Pharm-a-care was the sponsor and Pan was a manufacturer preventing the further supply of goods manufactured by Pan after 1 May 2002;

(iii) says that, in the thereafter, the operative decision was not Cesarin's decision referred to in paragraph 67 above, but was the delegate of the Minister's decision referred to in the preceding subparagraph.

**Sponsor Voluntary Recall**

112 The Commonwealth denies the allegations in paragraph 112 of the FASC.

113 In answer to paragraph 113 of the FASC, the Commonwealth:

(a) says that the "Sponsor Voluntary Recall" (as defined in the FASC) does not involve an exercise of power by Cesarin under the TG Act or at common law;

(b) says that the "Sponsor Voluntary Recall" (as defined in the FASC) does involve an exercise of the executive capacities of the Commonwealth;

(c) says that the "Sponsor Voluntary Recall" (as defined in the FASC) does not involve an exercise of power by Cesarin capable of engaging the tort of misfeasance in public office;

(d) otherwise does not admit the allegations in paragraph 113 of the FASC.

114 In answer to paragraph 114 of the FASC, the Commonwealth:

(a) repeats paragraph 113 above;

(b) otherwise does not admit the allegations in paragraph 114 of the FASC.

115 The Commonwealth denies the allegations in paragraph 115 of the FASC.

116 The Commonwealth denies the allegations in paragraph 116 of the FASC.

117 The Commonwealth denies the allegations in paragraph 117 of the FASC.

118 In answer to paragraph 118 of the FASC, the Commonwealth:

(a) denies the allegations in paragraph 118 of the FASC;

(b) repeats paragraph 85(b)(i) above and says further that:

(i) if (which is denied) the "Sponsor Voluntary Recall" (as defined in the FASC) is an exercise of power capable of engaging the tort of misfeasance in public office; then

(ii) Cesarin did not owe "Pan Suppliers" or "Pan Distributors" (as defined in the FASC) a duty to exercise the power to make the "Sponsor Voluntary Recall" legitimately;

(c) repeats paragraph 85(c)(i) above and says further that:

(i) if (which is denied) the "Sponsor Voluntary Recall" (as defined in the FASC) is an exercise of power capable of engaging the tort of misfeasance in public office; then

(ii) "Pan Suppliers" and "Pan Distributors" (as defined in the FASC) were not:

(A) identified or did not form an identifiable class at the time of Cesarin's decision to make the "Sponsor Voluntary Recall";

(B) were not directly affected by Cesarin's decision to make the "Sponsor Voluntary Recall".

**The Pan Consumer Warnings**

119 In answer to paragraph 119 of the FASC, the Commonwealth:

(a) repeats paragraph 68 above;

(b) otherwise does not admit the allegations in paragraph 119 of the FASC.

120 In answer to paragraph 120 of the FASC, the Commonwealth:

(a) says that the "Pan Warnings Direction" (as defined in the FASC), if it occurred (which is not admitted):

(i) does not involve an exercise of power by Slater, Maclachlan or Cesarin under the TG Act or at common law;

(ii) does involve an exercise of the executive capacities of the Commonwealth;

(iii) does not involve an exercise of power by Slater, Maclachlan or Cesarin capable of engaging the tort of misfeasance in public office;

(b) otherwise does not admit the allegations in paragraph 120 of the FASC.

121 In answer to paragraph 121 of the FASC, the Commonwealth:

(a) repeats paragraph 120 above;

(b) otherwise does not admit the allegations in paragraph 121 of the FASC.

122 The Commonwealth denies the allegations in paragraph 122 of the FASC.

123 The Commonwealth denies the allegations in paragraph 123 of the FASC.

124 The Commonwealth denies the allegations in paragraph 124 of the FASC.

125 The Commonwealth denies the allegations in paragraph 125 of the FASC.

126 In answer to paragraph 126 of the FASC, the Commonwealth:

(a) denies the allegations in paragraph 126 of the FASC;

(b) repeats paragraph 85(b)(i) above and says further that:

(i) if (which is denied) the "Pan Warnings Direction"(as defined in the FASC) is an exercise of power capable of engaging the tort of misfeasance in public office; then

(ii) Slater, Maclachlan and Cesarin did not owe "Injured Persons" a duty to exercise the power to make the "Pan Warnings Direction" legitimately;

(c) repeats paragraph 85(c)(i) above and says further that:

(i) if (which is denied) the "Pan Warnings Direction" (as defined in the FASC) is an exercise of power capable of engaging the tort of misfeasance in public office; then

(ii) "Injured Persons" (as defined in the FASC) were not:

(A) identified or did not form an identifiable class at the time of Slater, Maclachlan or Cesarin's decision to make the "Pan Warnings Direction";

(B) were not directly affected by Slater, Maclachlan or Cesarin's decision to make the "Pan Warnings Direction".

**Liability of the TGA Officers**

127 The Commonwealth denies the allegations in paragraph 127 of the FASC.

128 The Commonwealth denies the allegations in paragraph 128 of the FASC.

129 The Commonwealth denies the allegations in paragraph 129 of the FASC.

130 The Commonwealth denies the allegations in paragraph 130 of the FASC.

131 The Commonwealth denies the allegations in paragraph 131 of the FASC.

**Alternative to Cesarin Misfeasances**

132 The Commonwealth does not plead to paragraph 132 of the FASC because that paragraph contains no allegations.

133 The Commonwealth denies the allegations in paragraph 133 of the FASC.

134 The Commonwealth denies the allegations in paragraph 134 of the FASC.

135 In answer to paragraph 135 of the FASC, the Commonwealth:

(a) says that the "Pan Recommendations" (as defined in the FASC), if it occurred (which is denied):

(i) does not involve an exercise of power by Slater, Maclachlan, Tribe or Fraser under the TG Act or at common law;

(ii) does involve an exercise of the executive capacities of the Commonwealth;

(iii) does not involve an exercise of power by Slater, Maclachlan, Tribe or Fraser capable of engaging the tort of misfeasance in public office;

(b) otherwise does not admit the allegations in paragraph 135 of the FASC.

136 In answer to paragraph 136 of the FASC, the Commonwealth:

(a) repeats paragraph 135 above;

(b) otherwise does not admit the allegations in paragraph 136 of the FASC.

137 The Commonwealth denies the allegations in paragraph 137 of the FASC.

138 The Commonwealth denies the allegations in paragraph 138 of the FASC.

139 The Commonwealth denies the allegations in paragraph 139 of the FASC.

140 The Commonwealth denies the allegations in paragraph 140 of the FASC.

141 In answer to paragraph 141 of the FASC, the Commonwealth:

(a) denies the allegations in paragraph 141 of the FASC;

(b) repeats paragraph 85(b)(i) above and says further that:

(i) if (which is denied) the "Pan Recommendations" (as defined in the FASC) is an exercise of power capable of engaging the tort of misfeasance in public office; then

(ii) Slater, Maclachlan, Tribe and Fraser did not owe the "Injured Persons" a duty to exercise the power to make the "Pan Recommendations" legitimately;

(c) repeats paragraph 85(c)(i) above and says further that:

(i) if (which is denied) the "Pan Recommendations" (as defined in the FASC) is an exercise of power capable of engaging the tort of misfeasance in public office; then

(ii) the "Injured Persons" (as defined in the FASC) were not:

(A) identified or did not form an identifiable class at the time of Slater, Maclachlan, Tribe and Fraser's decision to make the "Pan Recommendations";

(B) were not directly affected by Slater, Maclachlan, Tribe and Fraser's decision to make the "Pan Recommendations".

142 In answer to paragraph 142 of the FASC, the Commonwealth:

(a) repeats paragraph 111(d) above;

(b) otherwise denies the allegations in paragraph 142 of the FASC.

**Vicarious liability of the Commonwealth**

143 The Commonwealth denies the allegations in paragraph 143 of the FASC and says further that:

(a) an exercise of a power under sections 28, 30 and/or 41 of the TG Act is an independent discretion vested in the Secretary or her delegate for which the Commonwealth cannot, at law, be vicariously liable;

(b) the conduct alleged against Slater, Maclachlan, Tribe, Fraser and Cesarin in the FASC, if proved, would constitute deliberate wrongdoing involving *inter alia* the entry by those persons into an unlawful conspiracy to injure and/or a conspiracy by unlawful means for which the Commonwealth is not and cannot at law be vicariously liable.

144 The Commonwealth denies the allegations in paragraph 144 of the FASC.

**Loss and damage**

145 The Commonwealth denies the allegations in paragraph 145 of the FASC and:

(a) says that the causal connection between any wrongdoing in connection with the decision of Cesarin to impose the condition referred to in paragraph 67 above in respect of Pharm-a-care (which is denied) and the loss and damage thereby suffered by Pharm-a-care (which is not admitted) was broken by the matters referred to in paragraph 111(d) above;

(b) says that even if there was any wrongdoing by any of the respondents (which is denied) and if the applicants have suffered loss (which is not admitted), such loss was not caused by any of the respondents but was caused by Pan by reason of:

(i) Pan's failure to comply with GMP, as identified in either or both the Travacalm Audit Report or the Pan Audit Report;

(ii) Pan's willingness (including by its most senior executives, Selim and Brennan) to engage in dishonest and improper conduct in relation to the manufacturing of therapeutic goods, including in its dealings with customers and the TGA, as pleaded at paragraphs 33, 34, 36, 38, 40, 41, 49, 57, 74 above and paragraphs 147, 148, 149, 150, 151, 152, 153, 154 and 156 below;

(c) says that the applicant could not have, consistently with its obligations to its shareholders and customers, properly and reasonably continued to source therapeutic goods for ultimate supply to consumers from Pan after it became aware of the GMP deficiencies at Pan disclosed in either or both the Travacalm Audit Report and the Pan Audit Report;

(d) says that regardless of any decisions or actions by Maclachlan, Cesarin or anyone else with authority under the TG Act, once the applicant became aware of the GMP deficiencies at Pan disclosed in either or both the Travacalm Audit Report and the

Pan Audit Report, it would have, consistent with its obligations to its shareholders and customers:

(i) ceased acquiring therapeutic goods from Pan;

(ii) carried out a voluntary recall of all goods they had supplied that had been sourced from Pan;

(iii) sought alternative sources of supply from the other manufacturers;

(e) says that if Pan had been given any notice of the decisions made Maclachlan and Cesarin on 28 April 2003, Pan would not have resisted successfully any further regulatory action because there were no submissions that were reasonably open to Pan to resist such action.

## F. NEGLIGENCE

### Alleged "February Audit"

146 In answer to paragraph 146 of the FASC, the Commonwealth:

(a) repeats paragraph 41 above;

(b) says that there was no "February Audit Report" as alleged, only drafts of an audit report recording the findings of an incomplete GMP audit of Pan which took place on 24 and 25 February 2003 and which, upon completion of that audit on 7 – 14 April 2003, were incorporated into the Pan Audit Report;

(c) says that the critical deficiencies identified in the draft audit report as at 21 March 2003 were grouped under five headings as follows:

(i) data manipulation;

(ii) schedule of conditions (to the company's manufacturing licence);

(iii) controls for ensuring compliance with conditions or registration-listing (ie marketing authorisation(s)) were regarded as critically deficient;

(iv) process control was regarded as critically deficient;

(v) release for supply was regarded as critically deficient;

(d) otherwise does not admit the allegations in paragraph 146 of the FASC.

**Alleged "April Audit"**

147 In answer to paragraph 147 of the FASC, the Commonwealth:

(a) says that the critical deficiencies identified in the Pan Audit Report were grouped under nine headings as follows:

(i) "Data Manipulation";

(ii) "Results Fabrication";

(iii) "Substitution";

(iv) "Deficient Raw Materials and Finished Product Controls";

(v) "The Conditions of Licence to Manufacture Therapeutic Goods";

(vi) "Schedule of Conditions (To the Company's Licence to Manufacture Therapeutic Goods)";

(vii) "Controls for Ensuring Compliance with Conditions of Registration or Listing (ie., Marketing Authorisation(s)) were Regarded as Critically Deficient";

(viii) "Process Control was Regarded as Critically Deficient";

(ix) "Inadequate Assurance Regarding Mix-Up +/- (Cross) Contamination";

(b) otherwise does not admit the allegations in paragraph 147 of the FASC and relies on the Pan Audit Report for its full force and effect.

***First critical deficiency: Data manipulation***

148 In answer to paragraph 148 of the FASC, the Commonwealth:

(a) says that the falsification or misrepresentation of analytical results is identified as an instance of a critical deficiency in SOP 401.8;

(b) says that the four instances of data manipulation identified in the Pan Audit Report were additional to the five instances noted in the Travacalm Audit Report;

(c) says that in addition to the 9 instances of data manipulation identified in the Travacalm Audit Report and the Pan Audit Report, there are at least 20 other identifiable instances of data manipulation which occurred at Pan and which were not known to the TGA at the time of the Travacalm audit or the GMP audit of Pan which occurred in February and April 2003, being:

(i) the 16 instances of data manipulation identified in the "Chromatograms Investigation" document referred to in paragraph 36(c) above;

(ii) data manipulation in relation to the following products: Favit Women Beauty Skin Plan (batch 79323), Favit Women Beauty Skin Plan (batch 81384), Favit Women Beauty Skin Plan (batch 81385) and Favit Women Beauty Skin Plan (batch 72142);

(d) repeats paragraphs 33(f) to (j), 36(c) and 74(r) and (s) above and says further that:

(i) the analyst's worksheet containing the record of manipulated data for Daily-Stress Bi-Layer tablets (batch 80754) (identified as an instance of data manipulation in the Pan Audit Report) is not in Jain's handwriting, but is in the handwriting of Fernandez;

(ii) the analyst's worksheet containing the record of manipulated data for Favit Women Beauty Skin Plan (batch 72142) (identified as an instance of data manipulation in paragraph (c)(ii) above) is not in Jain's handwriting, but is in the handwriting of Fernandez;

(e) says that the fourth instance of data manipulation identified in the Pan Audit Report (Night Formula batch 83062) was identified as an anticipated deficiency in the document entitled "Anticipated Deficiencies from Photocopied Documents" prepared by Elia in late February 2003 and referred to at paragraph 40(l) and 41(c) above;

(f) says that Pan's SOP 119 "Security Major on HPLC Software (Empower and Millennium Software)", which is referred to in subparagraphs (c) and (d) of paragraph 148 of the FASC, was reviewed and assessed as incomplete in the "Response Assessment and Corrective Action Status Report" prepared by Fraser on or about 31 March 2003 and supplied by Gould to Pan on 9 April 2003 for reasons identified therein;

(g) says that nothing alleged in paragraph 148 of the FASC detracts from the status of the matters appearing as the first critical deficiency in the Pan Audit Report as critical deficiencies;

(h) otherwise does not admit the allegations in paragraph 148 of the FASC.

***Second critical deficiency: Results fabrication***

149 In answer to paragraph 149 of the FASC, the Commonwealth:

(a) repeats paragraph 148(a) above;

(b) says that Fraser had been advised of the matters appearing as the second critical deficiency in the Pan Audit Report by Elia on the evening of 9 April 2003 as pleaded in paragraph 49(g) above;

(c) says that on 26 March 2003 Dhumal recorded in his diary "[r]eceived many results from Amdel for cod liver oil. Amdel tested vitamin A from cod liver oil. Told John [Brennan] that few batches have 160% result & 89% results. John Instructed me to report around 110% and not to report 160% or 89% results";

(d) says that the fabricated results referred to as part of the second critical deficiency in the Pan Audit Report were created by Dhumal as a result of the instruction of Brennan referred to in subparagraph (c) above;

(e) says that it was the regular practice of Brennan to instruct Pan staff (including Dhumal) to substitute out of specification results of testing conducted by external testers (such as Amdel) with test results which were within specification;

(f) says that nothing alleged in paragraph 149 of the FASC detracts from the status of the matters appearing as the second critical deficiency in the Pan Audit Report as critical deficiencies;

(g) otherwise does not admit the allegations in paragraph 149 of the FASC.

***Third critical deficiency: Substitution***

150 In answer to paragraph 150 of the FASC, the Commonwealth:

(a) says that it is a fundamental principle of the GMP Code that a manufacturer of therapeutic goods manufacture those therapeutic goods strictly in accordance with the marketing authorisation and not substitute for the ingredients of a therapeutic good approved on the ARTG other or different ingredients;

**Particulars**

(i) 2002 GMP Code: Chapter 1, Principle, clauses 1.2(iv), 1.2(vi), 1.3, 1.3(iii)(d) and 7.9.

(ii) 1990 GMP Code: clauses 600, 800 and 803.

(b) says that a sponsor of a therapeutic product cannot legitimately request a manufacturer of that product to manufacture the therapeutic product other than in accordance with its marketing authorisation and the conditions for its registration or listing on the ARTG;

(c) repeats paragraph 9(h) above and says further that:

(i) pursuant to section 16 of the TG Act and regulation 11 of the Therapeutic Goods Regulations 1990, a therapeutic good which is a listable good is separate and distinct from other therapeutic goods if it has *inter alia* a different active ingredient or a different excipient;

(ii) in the premises, the matters constituting the third critical deficiency in the Pan Audit Report constituted an offence by Pan under section 21 of the TG Act;

(d) says that:

(i) microbiological testing can only exclude risks of bovine spongiform encephalopathy (**BSE**) or "Mad Cow disease" when that testing is undertaken on the brain tissue of a dead cow;

(ii) China is not and never has been declared to be a "BSE Free" country;

(e) says that the matters constituting the third critical deficiency in the Pan Audit Report were identified as an anticipated deficiency in the document entitled "Anticipated Deficiencies from Photocopied Documents" prepared by Elia in late February 2003 and referred to at paragraph 40(l) and 41(c) above;

(f) says that the substitution by Pan of the ingredients for a therapeutic good on the ARTG with other ingredients not approved in relation to that therapeutic good (known as "doctoring") was an entrenched practice at Pan and recognised as a "massive ongoing deficiency";

**Particulars**

(i) Report of Elia to Selim dated 18 July 2000.

(ii) The matters appearing as the third and seventh critical deficiency in the Pan Audit Report.

(iii) Further particulars may be provided prior to trial.

(g) denies that the matters in paragraph 150(e) of the FASC disclose any error in the Pan Audit Report;

(h) says that nothing alleged in paragraph 150 of the FASC detracts from the status of the matters appearing as the third critical deficiency in the Pan Audit Report as critical deficiencies;

(i) denies the allegations in paragraph 150 of the FASC.

***Fourth critical deficiency: Deficient Raw Material & Finished Product***

151 In answer to paragraph 151 of the FASC, the Commonwealth:

(a) says that adequate testing of raw materials prior to production to ensure the identity, quality and dependability of those materials used in the manufacture of therapeutic goods is a fundamental principle of the GMP Code;

**Particulars**

(i) 2002 GMP Code: clause 1.2, 1.3, 1.4, 2.6, 2.7, 5.30.

(ii) 1990 GMP Code: clauses 600, 602, 647, 804, 805, 812 and 813.

(b) says that the approval of raw materials for use in production and the release for supply of the goods manufactured using those raw materials prior to their testing was an established practice at Pan;

**Particulars**

(i) See the matters in paragraphs 4.2, 4.3, 4.6 and 4.7 of the Pan Audit Report.

(ii) Further particulars will be provided prior to trial.

(c) says that Fraser had been advised of the matters appearing as the fourth critical deficiency in the Pan Audit Report by Elia on the evening of 9 April 2003 as pleaded in paragraph 49(g);

(d) denies the allegations in paragraph 151 of the FASC.

***Fifth critical deficiency: Conditions of licence to manufacture therapeutic goods***

152 In answer to paragraph 152 of the FASC, the Commonwealth:

(a) repeats paragraphs 149 and 151 above;

(b) says that at all material times until 17 April 2003 Brennan regularly overrode the decision of Pan's Quality Assurance Manager (Elia) and Pan's Quality Control Manager (Dhumal) or other Pan staff to reject raw materials or finished products on

the basis that they were not of sufficient quality or were not within specification in order to authorise the use of the raw materials in production or the release of the finished products for supply to the sponsor;

**Particulars**

(i) Instances appear in paragraphs 4.3 and 4.7 of the Pan Audit Report.

(ii) Further particulars may be provided prior to trial.

(c) says that on 17 April 2003 Selim issued a memorandum stating that "This memo supersedes all previous correspondence on this subject. The Quality Assurance Manager will have the final decision on Acceptance or Rejection of all raw materials and finished goods";

(d) denies the allegations in paragraph 152 of the FASC.

***Sixth critical deficiency: Breach of conditions of licence***

153 In answer to paragraph 153 of the FASC, the Commonwealth:

(a) says that Selenium 25ug did come within the restriction to Pan's licence imposed on 5 February 2003 and pleaded in paragraph 34(f)(ii) above because TGO 56 and the BP required the product be subject to a uniformity of content test as it:

(i) had under 2 milligrams of active content or the active content was less than 2% of the total mass;

(ii) was not a multi-vitamin or mineral product;

(b) says that section 3 of the TG Act defines "manufacture" to include releasing goods for supply;

(c) says that the goods referred to as part of the sixth critical deficiency in the Pan Audit Report were recalled by Pan only after their wrongful supply had been drawn to Pan's attention during the course of the GMP audit on Pan's premises on 24 and 25 February 2003;

(d) says that on 4 March 2003 Selim authorised the supply of a product, being a batch of cold tablets for a sponsor known as API, and Pan supplied those tablets to the sponsor, despite Elia drawing to Selim's attention that the supply of those tablets would be a breach of the restriction to Pan's licence imposed on 5 February 2003 and pleaded in paragraph 34(f)(ii) above;

(e) otherwise denies the allegations in paragraph 153 of the FASC.

***Ninth critical deficiency: cross contamination***

154 In answer to paragraph 154 of the FASC, the Commonwealth:

(a) denies the allegations in paragraphs 154(d), (e) and (f);

(b) says that SOP 401.8 identifies as an example of a critical deficiency a cleaning program not followed combined with dirty premises / equipment;

(c) says that Fraser had been advised of the matters appearing as the ninth critical deficiency in the Pan Audit Report by Elia on the evening of 9 April 2003 as pleaded in paragraph 49(g);

(d) says that nothing alleged in paragraph 154 of the FASC detracts from the status of the matters appearing as the ninth critical deficiency in the Pan Audit Report as critical deficiencies;

(e) otherwise does not admit the allegations in paragraph 154 of the FASC.

155 The Commonwealth denies the allegations in paragraph 155 of the FASC.

156 In answer to paragraph 156 of the FASC, the Commonwealth:

(a) denies the matters in paragraphs 156(a)(i), (ii), (v) and (vii) of the FASC;

(b) in answer to paragraph 156(b) of the FASC says that:

(i) between 28 August 2002 and 27 August 2003, before any audit by the TGA of the manufacturing practices of a person holding a manufacturing licence, the TGA officers conducing the audit asked the entity holding a

manufacturing licence under the TG Act whether it wanted the audit to proceed pursuant to the 1990 GMP Code or the 2002 GMP Code;

(ii) if the entity holding a manufacturing licence under the TG Act wanted the audit to proceed pursuant to the 1990 GMP Code, any matters identified during the audit which were in breach of the 2002 GMP Code but not the 1990 GMP Code were noted as such in the audit report prepared by the TGA;

(iii) if the entity holding a manufacturing licence under the TG Act wanted the audit to proceed pursuant to the 2002 GMP Code, any matters identified during the audit which were in breach of the 2002 GMP Code were noted as contraventions of the 2002 GMP Code in the audit report prepared by the TGA;

(iv) Fraser advised Brennan at the opening of the Travacalm audit and advised Selim and Brennan at the opening of the audit of Pan on 24 and 25 February 2003 and advised Selim and Elia at the opening of the continuation of that audit on 7 April 2003 that he proposed to audit Pan against the 2002 GMP Code;

(v) Pan did not object to being audited under the provisions of the 2002 GMP Code;

(vi) each critical deficiency identified in the Pan Audit Report was a critical deficiency under both the 1990 GMP Code and the 2002 GMP Code;

(c) says that nothing alleged in paragraph 156 of the FASC detracts from the correctness of the conclusions reached in the Pan Audit Report;

(d) otherwise does not admit the allegations in paragraph 156 of the FASC.

157 In answer to paragraph 157 of the FASC, the Commonwealth:

(a) repeats paragraph 146 above;

(b) otherwise does not admit the allegations in paragraph 157 of the FASC.

158 In answer to paragraph 158 of the FASC, the Commonwealth:

(a) repeats paragraph 146 above;

(b) otherwise denies the allegations in paragraph 158 of the FASC.

159 In answer to paragraph 159 of the FASC, the Commonwealth:

(a) says that at and from 30 April 2003 Pan:

(i) accepted that the critical deficiencies identified in the Pan Audit report were correct, or substantially correct, and that there was no prospect of impugning to any substantial degree the Pan Audit Report by alternative expert opinion;

(ii) accepted that the regulatory action taken by Maclachlan and Cesarin on 28 April 2003 in relation to Pan and the therapeutic goods manufactured by Pan based on the findings of the Pan Audit Report was justified;

**Particulars**

(i) Facsimile of Aitken, Maclachlan & Thorpe to Pan dated 30 April 2003.

(ii) Document entitled "Action Plan and Response" dated 30 April 2003 given by Pan to the TGA.

(iii) Press Release issued by Pan on 30 April 2003.

(b) denies the allegations in paragraph 159 of the FASC.

**The EAG Meeting**

160 In answer to paragraph 160 of the FASC the Commonwealth:

(a) admits that the EAG Meeting took place on 23 April 2003 at a meeting room at the Qantas Club at Sydney Airport;

(b) otherwise does not admit the allegations in paragraph 160 of the FASC.

161 In answer to paragraph 161 of the FASC, the Commonwealth:

(a) repeats paragraph 54(f) above;

(b) otherwise does not admit the allegations in paragraph 161 of the FASC.

162 In answer to paragraph 162 of the FASC, the Commonwealth:

(a) repeats paragraphs 55(a) and (b) above;

(b) otherwise does not admit the allegations in paragraph 162 of the FASC.

163 In answer to paragraph 163 of the FASC, the Commonwealth:

(a) says that the EAG were provided with the following documents:

(i) a paper entitled "Problems with compliance with the Code of Good Manufacturing Practice by a manufacturer of medicines in Australia";

(ii) the 5 February 2003 letter from Maclachlan to Pan referred to in paragraph 34 above;

(iii) the Travacalm Audit Report;

(iv) a draft of the Pan Audit Report;

(v) a document entitled "Product range manufactured by Pan Pharmaceuticals Ltd";

(b) says that Fraser explained orally to the EAG the findings of contained in the Travacalm Audit Report and the draft of the Pan Audit Report;

(c) repeats paragraph 56(b) above;

(d) otherwise does not admit the allegations in paragraph 163 of the FASC

164 In answer to paragraph 164 of the FASC, the Commonwealth:

(a) repeats the conclusions of the EAG Report pleaded in paragraph 57 above;

(b) relies on the conclusions in the EAG Report for their full force and effect;

(c) says that the conclusions in the EAG Report were unanimous;

(d) otherwise denies the allegations in paragraph 164 of the FASC.

165 In answer to paragraph 165 of the FASC, the Commonwealth:

(a) says that the issues on which the EAG was asked to advise were to the following effect:

(i) whether any of the GMP-related problems identified in the Travacalm Audit Report and the draft Pan Audit Report create an imminent risk of death, serious illness or serious injury to any member of the public;

(ii) in particular, whether any of the problems identified with individual products create an imminent risk of death, serious injury or serious illness;

(iii) further, whether, given the range of products Pan manufactures, if any of the poor manufacturing practices identified in the Travacalm Audit Report and the draft Pan Audit Report were applied to any of the products, this would create an imminent risk of death, serious illness or serious injury to any member of the community;

(iv) whether any of the problems identified with individual products, or problems which may potentially be associated with classes of products due to poor standards of manufacture identified in the Travacalm Audit Report and the draft Pan Audit Report, lead to their quality, safety or efficacy being unacceptable.

(b) says that qualifications or experience in GMP were unnecessary and irrelevant for the purpose of answering the questions on which the EAG was asked to advise;

(c) repeats paragraphs 148 to 159 above and denies that the Pan Audit Report suffered from the defects as alleged or at all;

(d) says that Pan had no right, entitlement or legitimate expectation of being present at the meeting of the EAG, or of presenting information to the EAG (either by itself or through an independent expert) or to be heard in relation to or challenge the views being expressed at the EAG Meeting;

(e) otherwise denies the allegations in paragraph 165 of the FASC.

166 The Commonwealth denies the allegations in paragraph 166 of the FASC and:

(a) repeats paragraphs 30, 41, 48(d), 146 and 156(b);

(b) says further that in the period May 2002 to April 2003 there were 118 adverse drug reactions reported to the TGA attributed to products of which Pan was identified as a manufacturer on the ARTG, being:

(i) 87 adverse reactions attributable to Travacalm;

(ii) 31 attributable to other products, of which 9 involved allergic reactions, 12 involved organ damage, 2 involved infections and 8 involved other adverse reactions;

(c) says further that:

(i) in December 2002 the TGA published a document entitled "Supplementary Requirements for Therapeutic Goods for Minimising the Risk of Transmitting Transmissible Spongiform Encephalopathies (**TSEs**)" (**TSE Document**);

(ii) Item 4, Table 1 of the TSE Document contained a table which contained the results of a literature review carried out by the TGA which sought to determine the TSE risk of ingredient of animal origin;

(iii) the table appearing at Item 4, Table 1 of the TSE Document identified cartilage, collagen, milk and milk derivative products as involving a theoretical risk of TSE;

(iv) otherwise relies on the TSE Document for its full force and effect.

167 In answer to paragraph 167 of the FASC, the Commonwealth:

(a) repeats paragraph 57 above;

(b) otherwise denies the allegations in paragraph 167 of the FASC.

**Negligent sponsor voluntary recall**

168 The Commonwealth does not admit the allegations in paragraph 168 of the FASC.

169 In answer to paragraph 169 of the FASC, the Commonwealth:

(a) repeats paragraphs 13 to 31 above;

(b) otherwise does not admit the allegations in paragraph 169 of the FASC.

170 In answer to paragraph 170 of the FASC, the Commonwealth:

(a) repeats paragraph 9 above;

(b) otherwise does not admit the allegations in paragraph 170 of the FASC.

171 The Commonwealth denies the allegations in paragraph 171 of the FASC.

172 The Commonwealth denies the allegations in paragraph 172 of the FASC.

173 The Commonwealth does not admit the allegations in paragraph 173 of the FASC.

174 In answer to paragraph 174 of the FASC, the Commonwealth:

(a) repeats paragraphs 146 to 169 above;

(b) otherwise denies the allegations in paragraph 174 of the FASC.

175 The Commonwealth does not admit the allegations in paragraph 175 of the FASC.

176 In answer to paragraph 176 of the FASC, the Commonwealth:

(a) repeats paragraph 145 above;

(b) otherwise does not admit the allegations in paragraph 176 of the FASC.

**Negligent Pan Consumer Warnings**

177 The Commonwealth does not admit the allegations in paragraph 177 of the FASC.

178 The Commonwealth does not admit the allegations in paragraph 178 of the FASC.

179 In answer to paragraph 179 of the FASC, the Commonwealth:

(a) repeats paragraphs 13 to 31 above;

(b) otherwise does not admit the allegations in paragraph 179 of the FASC.

180 The Commonwealth denies the allegations in paragraph 180 of the FASC.

181 The Commonwealth denies the allegations in paragraph 181 of the FASC.

182 The Commonwealth does not admit the allegations in paragraph 182 of the FASC.

183 The Commonwealth denies the allegations in paragraph 183 of the FASC.

184 In answer to paragraph 184 of the FASC, the Commonwealth:

(a) repeats paragraphs 145, 181 and 183 above;

(b) otherwise does not admit the allegations in paragraph 184 of the FASC.

**Negligent Sponsor Prohibition on Supply**

185 The Commonwealth does not admit the allegations in paragraph 185 of the FASC.

186 In answer to paragraph 186 of the FASC, the Commonwealth:

(a) says that the repository of the powers under sections 28, 30 and 41 of the TG Act (which are defined in the FASC as the "TGA Action") was the Secretary or her delegate and not the Commonwealth;

(b) repeats paragraph 143(a) above;

(c) otherwise denies the allegations in paragraph 186 of the FASC.

187 In answer to paragraph 187 of the FASC, the Commonwealth:

(a) repeats paragraphs 13 to 31 and 186 above;

(b) otherwise denies the allegations in paragraph 187 of the FASC.

188 In answer to paragraph 188 of the FASC, the Commonwealth:

(a) repeats paragraphs 9 and 186 above;

(b) otherwise denies the allegations in paragraph 187 of the FASC.

189 The Commonwealth denies the allegations in paragraph 189 of the FASC.

190 The Commonwealth denies the allegations in paragraph 190 of the FASC.

191 The Commonwealth denies the allegations in paragraph 191 of the FASC.

192 In answer to paragraph 192 of the FASC, the Commonwealth:

(a) repeats paragraphs 145 and 185 to 191 above;

(b) otherwise does not admit the allegations in paragraph 192 of the FASC.

## G. DAMAGES AND MATTERS SPECIFIC TO THE APPLICANT

193 In answer to paragraph 193 of the FASC, the Commonwealth:

(a) repeats paragraph 2 above;

(b) admits that Pharm-a-care and Laboratories Pharm-a-care Pty Limited (**Laboratories Pharm-a-care**) were the sponsors of therapeutic goods on the ARTG in relation to which Pan was nominated as a manufacturer;

(c) otherwise does not admit the allegations in paragraph 193 of the FASC.

194 The Commonwealth does not admit the allegations in paragraph 194 of the FASC.

195 In answer to paragraph 195 of the FASC, the Commonwealth:

(a) says that on 28 April 2003 Cesarin sent letters to Pharm-a-care and Laboratories Pharm-a-care of the kind referred to in paragraphs 67(b)(i) and (ii) above;

(b) otherwise does not admit the allegations in paragraph 195 of the FASC.

196 In answer to paragraph 196 of the FASC, the Commonwealth:

(a) says that as at 2003 there was published a "Uniform Recall Procedure for Therapeutic Goods" 2001 edition;

(b) otherwise does not admit the allegations in paragraph 196 of the FASC.

197 The Commonwealth does not admit the allegations in paragraph 197 of the FASC.

198 In answer paragraph 198 of the FASC, the Commonwealth:

(a) admits that on 29 April 2003 Paul de Roubaix sent a facsimile to Cesarin;

(b) relies on the facsimile referred to in the preceding paragraph for its full force and effect;

(c) otherwise does not admit the allegations in paragraph 198 of the FASC.

199 The Commonwealth does not admit the allegations in paragraph 199 of the FASC.

200 The Commonwealth does not admit the allegations in paragraph 200 of the FASC.

201 In answer to paragraph 201 of the FASC, the Commonwealth:

(a) says that on 7 May 2003 a facsimile was sent to Pharm-a-care under the letterhead of the TGA the subject of which was "Recall of products manufactured by Pan Pharmaceuticals Ltd";

(b) relies on the facsimile referred to in the preceding paragraph for its full force and effect;

(c) otherwise does not admit the allegations in paragraph 201 of the FASC.

202 In answer to paragraph 202 of the FASC, the Commonwealth:

(a) says that on 13 May 2003 Cesarin sent to Pharm-a-care a notice under section 30A of the TG Act requiring Pharm-a-care to *inter alia* recover to a consumer level a therapeutic good called "Nature's Way Joint Food Glucosamine, Chondroitin & MSM Powder 250 grams";

(b) says that the therapeutic goods referred to in the notice of 13 May 2003 were not registered goods, or listed goods, or exempt goods or goods exempt under section 18A of the TG Act, or goods which were the subject of approval or authority under section 19 of the TG Act, or goods which were the subject of an approval under section 19A of the TG Act;

(c) says that the therapeutic goods referred to in the note of Cesarin of 13 May 2003 were manufactured and supplied to Pharm-a-care by Pan;

(d) says that, in the premises, the supply of the therapeutic goods referred to in the notice of 13 May 2003 by Pan to Pharm-a-care and by Pharm-a-care to any third party was unlawful by reason of sections 20 and 21 of the TG Act;

(e) otherwise denies the allegation in paragraphs 202 of the FASC.

203 In answer to paragraph 203 of the FASC, the Commonwealth:

(a) admits that from 28 April 2003 Pharm-a-care could not lawfully obtain supply of therapeutic goods from Pan;

(b) repeats paragraph 195 to 202 above;

(c) otherwise does not admit the allegations in paragraph 203 of the FASC.

204 The Commonwealth does not admit the allegations in paragraph 204 of the FASC.

205 In answer to paragraph 205 of the FASC, the Commonwealth:

(a) repeats paragraph 145 above;

(b) otherwise does not admit the allegations in paragraph 205 of the FASC.

206 In answer to paragraph 206 of the FASC, the Commonwealth:

(a) repeats paragraph 145 above;

(b) otherwise does not admit the allegations in paragraph 206 of the FASC.

## H. CIVIL LIABILITY ACT 2002 (NSW)

207 In further answer to the claims asserted in the FASC, the Commonwealth says that:

(a) the provisions of the *Civil Liability Act 2002* (NSW) (**CL Act**) apply in this proceeding by force of section 79 of the *Judiciary Act 1903* (Cth);

(b) the claims pleaded in the FASC based on the exercise of the powers in sections 28, 30 and 41 of the TG Act by Maclachlan and Cesarin on 28 April 2003 are:

(i) claims based on a breach of statutory duty by a public or other authority in connection with the exercise of or failure to exercise a function of that authority within the meaning of section 43 of the CL Act;

(ii) claims based on a public or other authority's exercise of, or failure to exercise, a special statutory power within the meaning of section 43A of the CL Act;

(c) in the premises, the exercise of the powers in sections 28, 30 and 41 of the TG Act by Maclachlan and Cesarin on 28 April 2003 does not:

(i) constitute a breach of a statutory duty;

(ii) give rise to civil liability,

unless, in the circumstances, it was so unreasonable that no authority could properly consider the exercise of the powers in sections 28, 30 and 41 of the TG Act to be a reasonable exercise of those powers;

(d) says that the exercise of the powers in sections 28, 30 and 41 of the TG Act by Maclachlan and Cesarin on 28 April 2003 was not so unreasonable that no authority having those powers could properly consider their exercise to be a reasonable exercise of those powers;

(e) in the premises, there can be no civil liability by reason of the exercise of the powers in sections 28, 30 and 41 of the TG Act by Maclachlan and Cesarin on 28 April 2003.

Date: 12 May 2010

**Francis Reginald Lawson**
Solicitor for the First Respondent

This pleading was prepared by John Sackar QC, Peter Brereton SC, Michael O'Meara and James Arnott, counsel.

**IN THE FEDERAL COURT OF AUSTRALIA**
**NEW SOUTH WALES DISTRICT REGISTRY**

No. NSD 1991 of 2008

**Pharm-a-Care Laboratories Pty Ltd** ACN 003 468 219

Applicant

**Commonwealth of Australia** & Others

Respondents

FORM 15B

**CERTIFICATE OF LEGAL REPRESENTATIVE**

(Order 11, rule 1B)

I, Francis Reginald Lawson, certify to the Court that, in relation to the pleading dated 12 May 2010, the factual and legal material available to me at present provides a proper basis for:

(a) each allegation in the pleading;

(b) each denial in the pleading;

(c) each non-admission in the pleading.

Date: 12 May 2010

**Francis Reginald Lawson**
Solicitor for the First Respondent

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